Shared-Care Guideline

Drug: Second-generation antipsychotics (amisulpride, aripiprazole, olanzapine, quetiapine, oral risperidone, cariprazine)

Indication: See individual preparations

Introduction

This shared prescribing guideline for the second generation antipsychotic medications listed above has been developed with due consideration to the appropriate NICE Clinical Guidelines (CG) e.g. Bipolar Disorder (CG185), Psychosis and Schizophrenia in Children and Young People (CG155), Psychosis and Schizophrenia in Adults (CG178), Schizophrenia- Aripiprazole (TA213), Bipolar Disorder- Adolescents (TA292) and local LSCMMG recommendations.

Due to the range of licensed indications for the individual antipsychotics, they may be prescribed to treat a number of different conditions

Dose & Administration

Drug	Licensed Indication/s	Dose
Amisulpride	Schizophrenia	Max daily dose of 1200mg
Aripiprazole	Schizophrenia in adults and in adolescents 15 years and older, moderate to severe manic episodes of Bipolar I Disorder in adults and adolescents aged 13 and over (up to 12 weeks treatment in adolescents), prevention of a new manic episode in patients who experienced predominantly manic episodes and whose manic episodes respond to aripiprazole treatment	Max daily dose of 30mg, although limited evidence of benefit above 15mg
Olanzapine	Treatment and prophylaxis of schizophrenia and moderate to severe manic episodes	Max daily dose of 20mg
Quetiapine	Schizophrenia, manic episodes associated with bipolar disorder, major depressive episodes in bipolar disorder, preventing recurrence in bipolar disorder in patients whose manic or depressive episode has responded to quetiapine treatment. XL only: Add on treatment of major depressive episodes	Dependent on indication. Max daily dose of 800mg
Risperidone	Schizophrenia, moderate to severe manic episodes associated with bipolar disorders, 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 risk of harm to self or others, short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment	2mg to 16mg depending on the indication
Cariprazine	Treatment of schizophrenia in adult patients **Please note:** LSCMMG has recommended that cariprazine should only be used as a second-line therapy (where clozapine is not appropriate) where predominantly negative symptoms have been identified as an important feature. **Please note:** cariprazine **will not be approved** for use by secondary care for **women of child bearing potential** unless highly effective contraception is being used and women prescribed a systemically acting hormonal contraceptive agree to use a second barrier method of contraception (see '**contraindications**' below)	The recommended starting dose of cariprazine is 1.5 mg once daily. Thereafter the dose can be increased slowly in 1.5 mg increments to a maximum dose of 6 mg/day.

Secondary Care (LSCFT) Responsibilities	1. Choice of antipsychotic drug will be made with due consideration to the principles in the relevant NICE clinical guidelines. 2. The choice of antipsychotic drug will be made jointly by the patient and clinician, following an informed discussion of relative benefits and side effect profiles of both first- and second-generation antipsychotic drugs and giving due consideration to these likely benefit, side effects, licensed indications and cost effectiveness. Advocates or carers will be consulted where appropriate. If an advance directive has been previously agreed, drug treatment will be in line with this wherever possible. 3. Physical health monitoring will be conducted according to Lancashire and South Cumbria NHS Foundation Trust (LSCFT) monitoring guidelines (see appendix 1). The responsibility for monitoring rests with LSCFT for the first twelve months. Thereafter a request can be made to pass monitoring to the GP as part of this shared care arrangement. When this is in place patients will be told about the need to attend for an annual physical health check at their GP surgery. Where a need is identified, patients will be supported to attend GP surgeries for the purposes of an annual physical health check by LSCFT staff. 4. LSCFT will share the results of any blood monitoring with primary care. 5. Following instigation of the drug the patient will be maintained on the second-generation antipsychotic for a minimum of three months to establish response and tolerability. During this period existing antipsychotic therapy will be rationalised, to ensure that first and second-generation antipsychotic drugs are not co-prescribed for extended periods. 6. During this assessment period medication will be supplied by the hospital. 7. After this period the patient will be reassessed in secondary care and a shared prescribing arrangement between primary and secondary care will be facilitated if: a. the illness has stabilised and b. side effects of the medication are manageable and c. concordance to the regime is established The shared prescribing arrangement between primary and secondary care to manage the patient will be adopted as follows: 1. The Shared Care template letter or equivalent information should be communicated by mental health services to the GP 2. The patient will be prescribed a further 28 days of medication by secondary care during this process to allow continuity of treatment and the GP will be advised of this. 3. The patient will be informed of the process. 4. Should a response from the GP not be forthcoming within 28 days, the LSCFT pharmacy team will be contacted. LSCFT pharmacy staff will contact the CCG medicines management team and ask for this to be followed up with the GP practice. Once all the above is in place and the GP has agreed to participate in the shared prescribing arrangements a record will be made in the patient's clinical record and the patient will be informed that their next supply of medication will be obtained from their GP. If an alternative second-generation antipsychotic medication is commenced in secondary care following referral back to the consultant, dose stabilisation, monitoring and shared prescribing arrangements should be followed as outlined above for the new drug. **ECG monitoring** The following second-generation antipsychotic drugs are noted to refer to ECG monitoring in their Summary of Product Characteristics (SPCs): amisulpride. SPC's are subject to change at any time based on new information. This list may not be a definitive or exhaustive list. Prescribers are directed to consult the relevant SPC directly before prescribing. Most SPC's are available from https://www.medicines.org.uk/emc The BNF makes the following caution relating to cardiovascular disease for all antipsychotics regardless of SPC https://bnf.nice.org.uk/drug-class/antipsychotic-drugs.html#cautions: "An ECG may be required, particularly if physical examination identifies cardiovascular risk factors, personal history of cardiovascular disease, or if the patient is being admitted as an inpatient."

Primary Care Responsibilities	
	1. The repeat prescription arrangements employed by the practice must be made clear to the patient in order to avoid any disruption in continuity of supply. 2. Consider referral back to secondary care (using the contact details provided) in the following circumstances: a. Suspected relapse b. Poor response to treatment c. Non-adherence to medication d. Intolerable side effects from medication e. Co-morbid substance misuse f. Risk to self or others 3. Identify those service users at increased risk of developing cardiovascular disease and/or diabetes and manage them using the appropriate NICE guidance for the prevention of these conditions. 4. Monitor the physical health of the service user on treatment at least annually, from month 24 onwards, focusing on cardiovascular disease risk assessment as described in 'Lipid Modification' (NICE Clinical Guideline 67). Clinicians should also be mindful of other general health conditions and at their discretion consider other physical health checks such as full blood count, renal and liver function tests. 5. Treat those diagnosed with diabetes and/or cardiovascular disease in primary care according to the appropriate NICE guidance 6. To send a copy of any physical health results to the care coordinator and/or psychiatrist as required in the NICE guideline e.g. by completion of the 'copy to….' section on the blood test forms

Monitoring Required in Primary Care	Annual monitoring of pulse, blood pressure, weight, waist circumference, fasting blood glucose, HbA1c or lipid profile and prolactin. Enquire about any side effects and assess adherence with medication. Clinicians should also be mindful of other general health conditions and at their discretion consider other physical health checks such as full blood count, renal and liver function tests		
Adverse Effects & contraindications	**Drug**	**Common side effects**	**Contraindications**
	Amisulpride	Insomnia, anxiety, agitation, hyperprolactinaemia displayed as gynaecomastia, amenorrhoea, galactorrhoea or sexual dysfunction EPSE's, hypotension, constipation, nausea, vomiting, dry mouth, weight gain	Hypersensitivity to ingredients, prolactin-dependent tumours, phaeochromocytoma children under 15 years old, lactation, woman of childbearing age unless using adequate contraception, concomitant medication which could induce torsade de pointes, combination with levodopa
	Aripiprazole	Insomnia, restlessness, headache, dizziness, anxiety, EPSEs, akathisia, somnolence/sedation, tremor, blurred vision, nausea, vomiting, constipation, dyspepsia, hypersalivation	Hypersensitivity to Aripiprazole or any excipients
	Olanzapine	Somnolence, oedema, dizziness, fatigue, weight gain, increased appetite, eosinophilia, elevated glucose, elevated triglycerides, elevated cholesterol, glycosuria, akathisia, parkinsonism, dyskinesia, rash, sexual dysfunction, orthostatic hypotension, anticholinergic effects, elevation in liver enzymes, asthenia and oedema, increased prolactin levels	Hypersensitivity to any ingredient Known risk of narrow-angle glaucoma
	Quetiapine	Somnolence, dizziness, constipation, headache, dyspnea, dyspepsia, vomiting, weight gain, nightmares, orthostatic hypotension, tachycardia, palpitations, peripheral oedema. dry mouth, blurred vision, liver enzyme abnormalities, increases in blood glucose, decreased haemogolobin, eosinophilia, leucopenia, decreased neutrophil count, thyroid function test abnormalities, elevated plasma tri-glyceride and cholesterol concentrations, decreased HDL cholesterol, hyperprolactinaemia, irritability, suicidal ideation	Hypersensitivity to any ingredient Concomitant administration of cytochrome P450 3A4 inhibitors, such as HIV-protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin
	Risperidone	Insomnia, agitation, anxiety, headache, sedation, blurred vision, weight gain, tachycardia, hypertension, abdominal pain, gastrointestinal effects, dry mouth, rash, musculoskeletal pain, urinary incontinence, oedema, pyrexia,respiratory tract infections, urinary tract infections, sinusitis, nasal congestion,dyspnoea, cough, epistaxis, depression, hyperprolactinaemia displayed as gynaecomastia, galactorrhea or sexual dysfunction, extra pyramidal side effects	Hypersensitivity to any ingredient
	Cariprazine	Weight increased, Decreased appetite, Increased appetite, Dyslipidaemia, Sleep disorders, anxiety, Akathisia, Sedation, Parkinsonism, Dizziness, Dystonia, Other extrapyramidal diseases and abnormal movement disorders, Vision blurred, Tachyarrhytmia, Hypertension, Nausea, Constipation, Vomiting, Hepatic enzyme, increased Blood creatine phosphokinase, increased Fatigue.	Hypersensitivity to the active substance or to any of the excipients. Concomitant administration of strong or moderate CYP3A4 **inhibitors.** Concomitant administration of strong or moderate CYP3A4 **inducers.** **Pregnancy** – manufacturer advises avoid. Additionally, the manufacturer advises **highly effective contraception in women of childbearing potential during treatment and for at least 10 weeks after the last dose; addition of barrier method recommended in women using systemically-acting hormonal contraceptives.**
Drug Interactions	Caution is needed with medication that may cause electrolyte imbalance or prolong the QTc interval Dose adjustments of some antipsychotics may be necessary if co-prescribed with significant hepatic enzyme inducers or inhibitors e.g. carbamazepine, fluvoxamine, fluoxetine, paroxetine, ketoconazole, itraconazole.		

This guidance does not replace the SPC's, which should be read in conjunction with this guidance.

Date Reviewed: March 2023
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Appendix 1: Physical Health Monitoring Requirements

Time Period	Responsibility	Monitoring Required
Prior to Initiation Blood tests and ECG conducted within the previous three months can be considered baseline tests	LSCFT	Weight* Waist Circumference* Pulse and blood pressure Fasting blood glucose or glycosylated haemoglobin (HbA1c), blood lipid profile and prolactin levels Assessment of any movement disorders Assessment of nutritional status, diet and level of physical activity. An electrocardiogram (ECG) if any of the following apply: 1. It is a requirement of the summary of product characteristics (SPC). The SPC can be accessed via the website http://www.medicines.org.uk/emc/ 2. A physical examination has identified specific cardiovascular risk (such as diagnosis of high blood pressure) 3. There is a personal history of cardiovascular disease or 4. The service user is being admitted as an inpatient.
First three months on treatment (Titration Phase)	LSCFT	Weight*, weekly for the first 6 weeks Routinely and systematically assess side effects to treatment, emergence of movement disorders and overall physical health particularly during the titration phase At twelve weeks: • Weight* • Pulse and blood pressure • Fasting blood glucose • HbA1c Blood lipid levels
At 12 months	LSCFT	Weight* Waist circumference* Pulse and blood pressure Fasting blood glucose or HbA1c, blood lipid and prolactin levels Side effects to treatment, emergence of movement disorders and overall physical health
At 24 months and annually thereafter	GP	Weight* Waist circumference* Pulse and blood pressure Fasting blood glucose or HbA1c, blood lipid and prolactin levels Side effects to treatment, emergence of movement disorders and overall physical health

***Weight and waist circumference must be plotted on a chart or in an electronic system that can generate graphs to facilitate monitoring of trends**

This monitoring does not negate the need for additional health checks at the professional discretion of the clinician e.g. checks for renal and liver function

Optional Shared Care Agreement form

Request by Specialist Clinician for the patient's GP to enter into a shared care agreement

PLEASE NOTE: The use of this form is not compulsory, but the same information must be communicated between the specialist service and primary care in advance of entering into a shared-care agreement.

Part 1 - To be signed by Consultant / Associate Specialist / Speciality Trainee or Specialist Nurse (who must be a prescriber)

Dear Doctor:	Click or tap here to enter text.
Name of Patient:	Click or tap here to enter text.
Address:	Click or tap here to enter text.
	Click or tap here to enter text.
	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Patient NHS Number:	Click or tap here to enter text.
Patient Hospital Number:	Click or tap here to enter text.
Diagnosed Condition:	Click or tap here to enter text.

I request that you prescribe:

(1) Click or tap here to enter text.
(2) Click or tap here to enter text.
(3) Click or tap here to enter text.
(4) Click or tap here to enter text.

for the above patient in accordance with the LSCMMG shared care guideline(s) (Available on the LSCMMG website).

Last Prescription Issued:	Click or tap to enter a date.
Next Supply Due:	Click or tap to enter a date.
Date of last blood test (if applicable):	Click or tap to enter a date.
Date of next blood test (if applicable:	Click or tap to enter a date.
Frequency of blood test (if applicable:	Click or tap here to enter text.

I confirm that the patient has been stabilised and reviewed on the above regime in accordance with the Shared Care guideline.

If this is a Shared Care Agreement for a drug indication which is unlicensed or off label, I confirm that informed consent has been received from the patient.

I will accept referral for reassessment at your request. The medical staff of the department are available if required to give you advice.

Details of Specialist Clinicians

Name:	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Position:	Choose an item.
Signature:	Click or tap here to enter text.

(An email from the specialist clinician will be taken as the authorised signature)
In all cases, please also provide the name and contact details of the Consultant.

When the request for shared care is made by a Specialist Nurse, it is the supervising consultant who takes medicolegal responsibility for the agreement.

Consultant	Click or tap here to enter text.

Contact Details

Telephone Number	Click or tap here to enter text.
Extension	Click or tap here to enter text.
Email Address	Click or tap here to enter text.

Part 2 - To be completed by Primary Care Clinician (GP)

I agree to prescribe and monitor Click or tap here to enter text. for the above patient in accordance with the LSCMMG shared care guideline(s) commencing from the date of next supply / monitoring (as stated in Part 1 of the agreement form).

Name:	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Signature:	Click or tap here to enter text.

*Please sign and return a copy **within 14 calendar days** to the address above* **OR**

If you **do not** agree to prescribe, please sign below and provide any supporting information as appropriate:

I **DO NOT** agree to enter in to a shared care agreement on this occasion.

Name:	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Signature:	Click or tap here to enter text.
Further information:	Click or tap here to enter text.