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 **Lower starting doses** in those with renal impairment may be required
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 **Lower starting doses** in the elderly or those with hepatic impairment may be required
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 **Lower starting doses** in the elderly or those with hepatic impairment may be required
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.

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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

Cautions listed for ALL antipsychotics – contraindications and cautions listed for individual drugs below

Blood dyscrasias; cardiovascular disease; conditions predisposing to seizures; depression; diabetes (may raise blood glucose); epilepsy; history of jaundice; myasthenia gravis; Parkinson's disease (may be exacerbated); photosensitisation (may occur with higher dosages); prostatic hypertrophy; severe respiratory disease; susceptibility to angle-closure glaucoma.

Cardiovascular disease
QT prolongation risk applies particularly to:

- Amisulpride
- Quetiapine
- Risperidone
- Olanzapine (caution)

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. **Urgent review required if syncope, palpitations, or unexplained dizziness occur.**

Elderly
Screening Tool of Older Persons' potentially inappropriate Prescriptions (STOPP) criteria to aid medication reviews is available in the BNF – see here and individual monographs in the BNF for further information.

Pregnancy and breastfeeding

For patients planning a pregnancy, newly pregnant, or breastfeeding, urgent advice should be sought from the specialist perinatal community mental health team (SPCMHT), either via referral or via advice and guidance as early as possible.

Contact details are:

Area/Service	Email	Phone
Central and West Lancashire	C&WLSpecialistPerinatalCMHT@lscft.nhs.uk	01772 520 733
North Lancashire and South Cumbria	NLandSC.SPCMHT@lscft.nhs.uk	01524 550 887
Pennine Lancashire	PennineSpecialistPerinatalCMHT@lscft.nhs.uk	01254 612 731

Additional information is also available via the NHS North West Coast Clinical Network document 'Psychotropic Medications in the perinatal period'. Available via: Psychotropic-Medication-in-the-perinatal-period-NWC-PMH_v2.pdf

Important information:

Pregnancy:
Extrapyramidal effects and withdrawal syndrome have been reported occasionally in the neonate when antipsychotic drugs are taken during the third trimester of pregnancy. Following maternal use of antipsychotic drugs in the third trimester, neonates should be monitored for symptoms including agitation, hypertonia, hypotonia, tremor, drowsiness, feeding problems, and respiratory distress – **see also 'cariprazine' below.**

Breastfeeding:
There is limited information available on the short- and long-term effects of antipsychotic drugs on the breast-fed infant. *Animal studies* indicate possible adverse effects of antipsychotic medicines on the developing nervous system. Chronic treatment with antipsychotic drugs whilst breast-feeding should be avoided unless absolutely necessary. Phenothiazine derivatives are sometimes used in breast-feeding women for short-term treatment of nausea and vomiting.

Common side effects listed for ALL antipsychotics – common side effects for individual drugs listed below

Agitation; amenorrhoea; arrhythmias; constipation; dizziness; drowsiness; dry mouth; erectile dysfunction; fatigue; galactorrhoea; gynaecomastia; hyperglycaemia; hyperprolactinaemia; hypersalivation; hypotension (dose-related); insomnia; leucopenia; movement disorders; muscle rigidity; neutropenia; parkinsonism; postural hypotension (dose-related); QT interval prolongation; rash; seizure; tremor; urinary retention; vomiting; weight increased

	Drug	Very common or common side effects	Cautions and contraindications
	Amisulpride	Anxiety; breast pain; nausea; oculogyric crisis; orgasm abnormal; trismus; vision blurred.	**Contraindications:** Hypersensitivity to amisupride or any excipients . CNS depression; comatose states; phaeochromocytoma; prolactin-dependent tumours.
	Aripiprazole	Anxiety; appetite abnormal; diabetes mellitus; gastrointestinal discomfort; headache; musculoskeletal stiffness; nausea; vision disorders; weight decreased. **MHRA Drug Safety Update: Aripiprazole (Abilify and generic brands): risk of pathological gambling** Healthcare professionals prescribing aripiprazole are reminded to be alert to the risk of addictive gambling and other impulse control disorders. Healthcare professionals should advise patients, their families and friends to be alert to these risks.	**Contraindications:** Hypersensitivity to Aripiprazole or any excipients **Cautions:** Cerebrovascular disease; elderly (reduce initial dose); risk of aspiration pneumonia.

	Olanzapine	Anticholinergic syndrome; appetite increased; arthralgia; asthenia; eosinophilia; fever; glycosuria; oedema; sexual dysfunction. Hypersomnia (with oral use).	**Contraindications:** Hypersensitivity to any ingredient Known risk of narrow-angle glaucoma **Cautions:** Bone-marrow depression; hypereosinophilic disorders; low leucocyte count; low neutrophil count; myeloproliferative disease; paralytic ileus. **Further cautions and contraindications are associated with intramuscular use – see BNF for further details.**
	Quetiapine	Appetite increased; asthenia; dysarthria; dyspepsia; dyspnoea; fever; headache; irritability; palpitations; peripheral oedema; rhinitis; sleep disorders; suicidal behaviours; syncope; vision blurred; withdrawal syndrome. severe cutaneous adverse reactions (SCARs) can occur rarely – discontinue quetiapine immediately and organise an urgent specialist review.	**Contraindications:** Hypersensitivity to any ingredient Concomitant administration of cytochrome P450 3A4 inhibitors, such as HIV-protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin **Cautions:** Cerebrovascular disease; elderly; history or risk factors for sleep apnoea; patients at risk of aspiration pneumonia; treatment of depression in patients under 25 years (increased risk of suicide).
	Risperidone	Anaemia; anxiety; appetite abnormal; asthenia; chest discomfort; conjunctivitis; cough; depression; diarrhoea; dyspnoea; epistaxis; fall; fever; gastrointestinal discomfort; headache; hypertension; increased risk of infection; joint disorders; laryngeal pain; muscle spasms; nasal congestion; nausea; oedema; oral disorders; pain; sexual dysfunction; skin reactions; sleep disorders; urinary disorders; vision disorders; weight decreased.	**Contraindications:** Hypersensitivity to any Ingredient. **Cautions:** Avoid in acute porphyrias; cataract surgery (risk of intra-operative floppy iris syndrome); dehydration; dementia with Lewy bodies; prolactin-dependent tumours.
	Cariprazine	Anxiety; appetite abnormal; bradyphrenia; drooling; dyslipidaemia; eye disorders; gait abnormal; hypertension; joint stiffness; muscle tightness; musculoskeletal stiffness; nausea; oral disorders; pain; reflexes abnormal; sleep disorders; speech impairment; teeth grinding; vision disorders.	**Contraindications:** 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.** 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. **See below for individual drugs.** **Amisulpride** • QT-prolonging drugs – Avoid combination (e.g. class IA or III antiarrhythmics; other QT-prolonging antipsychotics; QT-prolonging antidepressants; macrolides; fluoroquinolones) • Levodopa and dopamine agonists – Avoid combination **Aripiprazole** • Strong CYP3A4 inducers (e.g. carbamazepine, phenytoin, rifampicin, St John's wort) – Avoid combination **Olanzapine** • Levodopa and dopamine agonists – Avoid combination **Quetiapine** • Strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin, protease inhibitors) – Avoid combination • Strong CYP3A4 inducers (e.g. carbamazepine, phenytoin, rifampicin, St John's wort) – Avoid combination **Risperidone** • Levodopa and dopamine agonists – Avoid combination **Cariprazine** • Strong CYP3A4 inhibitors (e.g. azole antifungals, macrolides, protease inhibitors) – Avoid combination • Strong CYP3A4 inducers (e.g. carbamazepine, phenytoin, rifampicin, St John's wort) – Avoid combination

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

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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