Berkshire West Integrated Care System

Representing

Berkshire West Clinical Commissioning Group Royal Berkshire NHS Foundation Trust Berkshire Healthcare NHS Foundation Trust Berkshire West Primary Care Alliance



Prescribing Guidelines

Prescribing arrangement for the management of patients transferring from Secondary Care to Primary Care

Prescribing and Monitoring of Oral Antipsychotics

APC PG [XXX]

For the latest information on interactions and adverse effects, always consult the latest version of the Summary of Product Characteristics (SPC), which can be found at: http://www.medicines.org.uk/

Approval and Authorisation

Approved by	Job Title	Date
BHFT Drugs and Therapeutics Committee	Dr M.Irani, Medical Director, Chair	09/07/2020
BW Prescribing Oversight Committee	G Braham, Chair	TBC
BE Medicines Optimisation Board	S Bellars, Chair	22/07/2020

Change History

Version	Date	Author	Reason
v.2.	July 2019	Ozma Tahir	New document
V.2.3.	June 2020	Ozma Tahir	Addition of flowchart and clarification of lurasidone formulary position.

This prescribing guideline remains open to review considering any new evidence.

This guideline should only be viewed online and will no longer be valid if printed off or saved locally

Author	Ozma Tahir	Date of production:	22/07/2020
Job Title	Lead Clinical Economy and Clinical Trials Pharmacist	Review Date	30/06/2022
Protocol Lead	Dr Sanjoo Chengappa	Version	v.1.0

Principles of Prescribing Arrangement



These prescribing Guidelines are a local policy to enable General Practitioners to accept responsibility for the prescribing and monitoring of medicines, treatments or devices in primary care, in agreement with the initiating specialist service.

This guideline provides a framework for the seamless transfer of care for a person from a hospital or specialist service setting to general practice, where this is appropriate and, in the patient's best interest. People should never be placed in a position where they are unable to obtain the medicines they need because of a lack of communication between primary and secondary care.

It is important to note, in line with the General Medical Council guidance on prescribing, doctors are responsible for prescriptions they sign, and their decisions and actions when they supply and administers medicines and devices; or authorise or instruct others to do so.

Transfer of care

Transfer of clinical responsibility to primary care should only be considered where the patient's clinical condition is stable or predictable.

Referral to the GP should only take place once the GP has agreed to this in **each individual case**, and the hospital or specialist will continue to provide prescriptions until a successful transfer of responsibilities. The GP should confirm the agreement and acceptance of the shared care prescribing arrangement and that supply arrangements have been finalised. The secondary care provider must supply an adequate amount of the medication to cover this transition period. The patient should then be informed to obtain further prescriptions from the GP.

Clinicians should clearly explain what a shared care arrangement means for the patient and why it might be an option in their case. The patient or their carers should have the opportunity to ask questions and explore other options if they don't feel confident that shared care will work for them. They should be fully involved in, and in agreement with, the decisions to move to a shared care model for their on-going care. **Importantly, patients should never be used as a conduit for informing the GP that the prescribing is to be transferred.**

Patient consent

The best interest, agreement and preferences of the patient should be at the centre of the decision to begin shared care and their wishes followed wherever possible. Patients should be able to decline shared care if, after due consideration of the options, they decide that it is not in their best interests. Involvement of carers may be critical, especially in circumstances when it is not possible for the patients to make a decision e.g. mental capacity; where appropriate they should be included in the discussion about shared care.

Background

This shared care protocol covers the use of oral antipsychotics prescribed for the treatment of:

Author		Date of production / Review Date:	
Job Title		Version	V.
Protocol Lead	[Secondary Care Specialist]	Page number	2 of 15



- Schizophrenia / schizoaffective disorder
- Bipolar affective disorder
- **Psychotic symptoms** i.e. hallucinations, thought disorder, paranoia, delusions, conceptual disorganisation, grandiosity and psychomotor agitation for those patients who do not have a diagnosis of schizophrenia/ schizoaffective disorder or bipolar disorder.
- Unlicensed indications approved by NICE; **psychotic depression, severe and distressing anxiety in bipolar disorder** where psychological treatment has failed.
- **Major depression** adjunctive treatment (Quetiapine XL is licensed; however, other atypical antipsychotics are used off-label).

This includes some unlicensed use of licensed medicines due to the variation is licensing for antipsychotics i.e. no medicine is licensed for 'schizoaffective' disorders, but antipsychotics are clearly required. Such use is covered by internal BHFT Unlicensed Use of Medicines policy (available on request).

NICE Guidelines (<u>CG178</u>) recommend that assessments for psychosis be carried out by a Consultant Psychiatrist. Similarly, NICE recommend (<u>CG185</u>) patients with mania or severe depression are referred to Specialist Mental Health assessment. For patients who have depression and are at risk of harm to self or others, then they must be referred to specialist mental health services (<u>CG90</u>).

See Appendix 1 and 2 for BHFT Formulary options and Management of Adverse Effects respectively.

BHFT acknowledge that Clinician decision making should involve Patients and so practice 'Value Based Prescribing.'

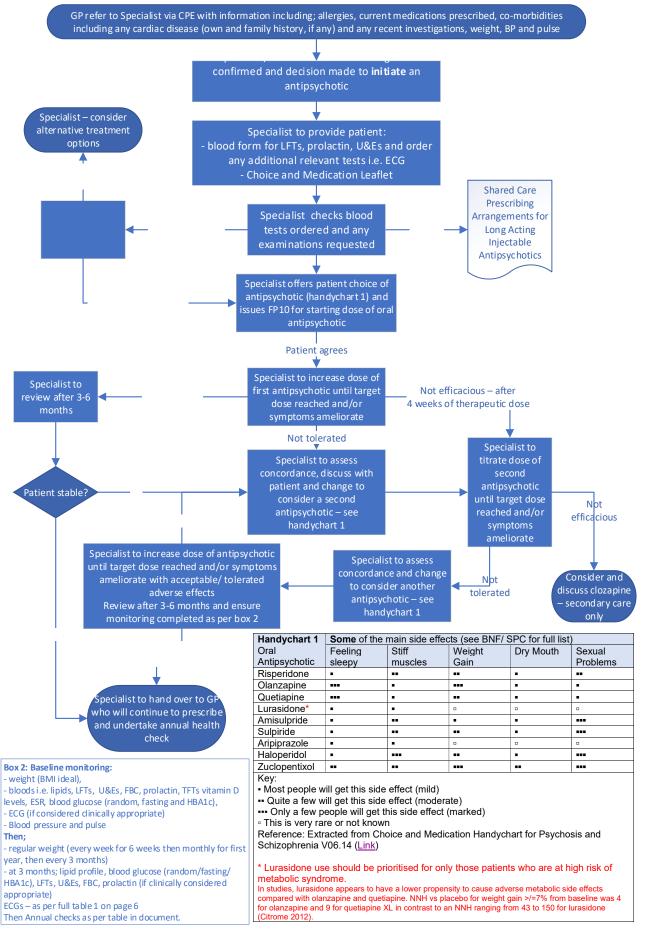
Patient groups with the following diagnoses are excluded from this shared care prescribing arrangement:

- Children and Adolescents aged below 18yrs
- Learning disabilities **BHFT support STOMP initiative**.
- Behavioural and Psychotics Symptoms of Dementia
- Patients prescribed clozapine
- Patients prescribed long acting injectable antipsychotics, for which there is a separate shared care agreement

Author		Date of production / Review Date:	
Job Title		Version	V.
Protocol Lead	[Secondary Care Specialist]	Page number	3 of 15

Pathway for antipsychotic prescribing





Author		Date of production / Review Date:	
Job Title		Version	V.
Protocol Lead	[Secondary Care Specialist]	Page number	4 of 15



Responsibilities

Specialist Team Responsibilities (Specialist / Psychiatrist)

General Responsibilities

Connected Care should be accessed for live updated clinical information including medication, allergies, cardiac history and status, in order to evaluate for individual risk and interactions in the first instance.

- Confirm patient's diagnosis and requirement for treatment with oral antipsychotics.
- Confirm patient's suitability for oral antipsychotic treatment in terms of co-morbidities etc. Document in notes clearly; patient's concordance to medication and preferences with regards to treatment. Also, document rationale for choice of treatment prescribed.
- Check medical history and co-morbidities for cautions, contraindications to medications and interactions with current medicines (if any).
- Check patients baseline blood tests (fasting lipids, blood glucose, LFT's, U&E's, FBC, prolactin) and other parameters like weight, BP and pulse.
- Assess patient's cardiovascular risk factors and request ECG from GP (if clinically indicated).
 - NB GPs are not always able to interpret an ECG seek Cardiologist advice where necessary.
- Where patient is suitable for treatment with an oral antipsychotic, ensure the process of shared care has been explained to the patient and they give their informed consent to the transfer of care to their GP
- Initiate the patient on oral antipsychotic in accordance with BHFT Formulary and arrange for follow-up appointments (via outpatient clinic/virtual clinics) to manage dose titration and appropriate monitoring
- The patient should be provided with written information and verbal information about the
 illness and treatments prescribed. Details of information provided must also be
 documented in the clinical notes. Patients can be referred to the BHFT Choice and
 Medication website as an independent reference source.
 http://www.choiceandmedication.org/berkshirehealthcare/
- Ensure the patient is reviewed 3-6 months or as clinically indicated after dose optimisation and review oral antipsychotic treatment if there is no improvement in symptoms
- Any dose changes once the patient is established on treatment will be conveyed in writing to the GP for the GP to prescribe
- Monitor side effects of medication via routine follow up
- Report adverse events to the CSM/MHRA via Yellow Card Reporting Scheme
- Check drug interactions with any current medication the patient is taking
- Supply the patient with enough oral antipsychotic treatment via an FP10 to cover the period
 of transfer to the GP. This needs to take in to account the period for the GP to accept the
 request
- If the GP does not accept the request to take prescribing responsibility, continuing treatment must be prescribed by the Specialist team.

Transfer of Prescribing Responsibilities

- Transfer of clinical responsibility to primary care should only be considered where the person's clinical condition is stable or predictable.
- Communicate to the patient's GP to request a transfer of prescribing responsibilities; detailing the drug, formulation, dose and frequency to be prescribed, along with details of how to refer back to the Community Mental Health Team (CMHT) should the patient develop a problem with their treatment.

Author		Date of production / Review Date:	
Job Title		Version	V.
Protocol Lead	[Secondary Care Specialist]	Page number	5 of 15



Disease Monitoring

- The patient will be reviewed by the Specialist Team when necessary. The time interval will differ depending on the individual patient.
- Communicate to the GP all necessary monitoring that needs to be carried out in primary care (detailed below).

Primary Care Team Responsibilities (General Practitioner)

Pre-referral to secondary care specialist service

To provide full history and details of presenting complaint including -

- Past and present medical and psychiatric symptoms
- Full physical assessment should include cardiovascular system examination, weight, blood pressure and heart rate.

If there is past medical or family history of serious cardiac disease, a history of sudden death in young family members or abnormal findings on previous cardiac examination, then provide ECG details (consult a cardiologist for clarification as needed).

- Risk assessment for substance misuse and drug diversion.
- 2. To provide a list of current medication, including formulation, dose and indications
- 3. To provide information about other co-morbidities

Post-Secondary Care review

- The GP will add the drug to the patient's repeat prescription after 2 weeks of receipt of the information from the Community Mental Health Team or Inpatient Clinician and issue ongoing prescriptions.
- Check drug interactions with any new medication started or any new conditions diagnosed. Contact the specialist team if interactions found and discuss with Consultant.
- Undertake drug specific monitoring, where applicable, as detailed below.
- Amend prescription as per requests from secondary care for dose changes in patients on established treatment.
- Where a change in medication or dose is required, for example if a drug/dose has not been tolerated, GP can contact the Psychiatrist or refer the patient back to their CMHT
- Report adverse events to the CHM/MHRA.
- Report adverse events to the consultant sharing the care of the patient.
- Follow specialist advice on any changes to treatment.
- Report and seek advice from specialist on any aspect of patient care which is of concern (i.e. refer to endocrinologists and /or psychiatrists if prolactin is considerably raised).
- The specialist will diagnose the patient & suggest the GP adds to the mental health register. The GP will undertake reviews as appropriate.

Routine Monitoring

- Annual blood tests checking; Lipid profile, blood glucose (fasting or HbA1c as considered clinically appropriate), Liver Function tests (LFTs), Urea and Electrolytes (U&Es), BP/Pulse.
- Annual weight and/or BMI checks
- ECGs, if clinically indicated (determined by presenting symptoms, cardiac risk factors, concurrent use of other QT prolonging agents etc.)

Disease Monitoring

- Notify the psychiatrist as soon as possible of any changes to drug treatment or change in presentation if appropriate.
- If patients are being managed under a Community Treatment Order (CTO), any changes to

Author		Date of production / Review Date:	
Job Title		Version	V.
Protocol Lead	[Secondary Care Specialist]	Page number	6 of 15



psychotropic medication prescribed must be reported to and be authorised by the Responsible Clinician.

GPs who have previously followed guidance from CMHT Psychiatrists and initiated / titrated patients on their oral antipsychotic treatment may continue provided this is within their scope of competence.

Patient's role (or that of carer)

- Ask the specialist or GP for information, if he or she does not have a clear understanding of the treatment.
- Tell the specialist or GP of any other medication being taken, including over-the-counter products.
- Read the patient information leaflet included with your medication and report any side effects or concerns you have to the specialist or GP
- Adhere to treatment as advised by the specialist.

Author		Date of production / Review Date:	
Job Title		Version	V.
Protocol Lead	[Secondary Care Specialist]	Page number	7 of 15



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T. 1.1. 4 M				
Table 1: Monitor	ring for ani	apsychotics	s (except	
clozapine)				
	Baseline*	3 months	Ongoing	Further information
Weight (include	✓	Weekly for 6	weeks, Monthly for the	
BMI ideally)		first year, the		
Lipid profile	✓	√	•	
			Annual	
Blood glucose	✓			
(random/fasting/		✓	Annual	
HBA1c)				
LFTs	✓	✓		
ECG				after dose increases and then
				risk factors, are taking other drugs
				oses. Consider baseline and annual
U&Es	ECG in othe	er patients whe	re indicated.	
FBC	V ✓	∨		To indicate neutropenia, anaemia,
FBC				B12 and folate deficiencies.
Prolactin	√	Check if sym	ntoms of	D12 and totate deficiencies.
1 Toluotiii		hyperprolacti		
		(menstrual di		
			a, gynaecomastia,	
		sexual dysfur		
Blood pressure	✓	Frequently du	ıring titration.	
and pulse				
Thyroid Function	✓			Thyroid abnormalities often lead to
Tests				changes in mental state and mood.
Vitamin D	√			Deficiencies may compromise
Folate	•			cognitive function and produce confusional states (folate
				deficiencies are not only implicated
				in the symptoms of psychosis, but
				can also reverse the beneficial
				effects of many antidepressants).
ESR	✓			
Drug Screen (if	✓			
appropriate)				
* Inpatient monitori	ng should be	e repeated in a	accordance with	
clinical need			languates by the C	
			long stay inpatient)	
 Initial baseline up to checked by Psychiat 		ter basellile SII	ould be ordered and	
- Annual checks sho		d over to the na	atient's GP	
Additional monitori		a over to the pe	AUDITO OF	
- Rapid Tranquilisation		requirements a	are covered in the	
Rapid Tranquilisation			··· ···	
- High Dose Antipsyo			requirements are	
covered in HDAT Ris	sk Manageme	nt Guideline.	•	
- Clozapine; please r	efer to separa	ate clozapine tr	eatment guideline	

Author		Date of production / Review Date:	
Job Title		Version	٧.
Protocol Lead	[Secondary Care Specialist]	Page number	8 of 15

Communication



All electronic forms of communication must be sent within 48 hours of a patient intervention (i.e. appointment/ discharge etc.)

Specialist to GP

The Consultant/Nurse **Mental Health Specialist** will inform the GP when they have initiated **oral antipsychotic treatment** and will provide a summary of dosage / instructions for the GP to follow.

GP to Specialist

If the GP has concerns over the prescribing of the relevant **oral antipsychotic treatment**, they will contact the **Specialist Mental Health Team** as soon as possible.

Contact Information

Community Mental Health Team (CMHT) contact details:

To discuss a patient or to request specialist advice, GPs can call their local CMHT using the following numbers:

Slough:		Reading:	
Adult CMHT Tel:	01753 690950	Adult CMHT Tel:	0118 960 5612
Older Adult CMHT	01753 634671	Older Adult	0118 960 5040
Tel:		CMHT:	
Bracknell:		Wokingham:	
Adult CMHT Tel:	01344 823333	Adult CMHT Tel:	0118 989 0707
Older Adult CMHT	01344 823220	Older Adult	0118 989 0707
Tel:		CMHT:	
Windsor &		Newbury:	
Maidenhead:	01628 640200	Adult CMHT Tel:	01635 292020
Adult CMHT Tel:	01628 640350	Older Adult	01635 292070
Older Adult CMHT:		CMHT:	

Common Point of Entry: 0300 365 0300

For antipsychotics medicines related enquiries, you can call our BHFT Medicines Information Service, which is open from 9am-1pm on Monday to Friday on 0118 9605075. Alternatively you can email your enquiry to medicines.information@berkshire.nhs.uk and we will respond to your enquiry within 1-2 working days.

References

- NHS England. 2018. Responsibility for prescribing between Primary & Secondary/Tertiary Care. Accessed via <u>https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/</u> on 16/3/2018.
- NICE Guideline CG 178 Psychosis and schizophrenia in adults: prevention and management. Last updated March 2014.
- 3. NICE Guideline CG185 Bipolar disorder: assessment and management. Last updated April 2018.
- 4. NICE Guideline CG90 Depression in adults: recognition and management. Last updated April 2018.
- 5. Maudsley Prescribing Guidelines 13th edition, 2018. South London and Maudsley NHS Foundation Trust. D.Taylor et al.
- Other shared care documents; Barnet and Haringey, Greater Manchester Medicines Management Group, Dorset.

Author		Date of production / Review Date:	
Job Title		Version	V.
Protocol Lead	[Secondary Care Specialist]	Page number	9 of 15



Appendix 1: Formulary Choices of Oral Antipsychotics and licensed indications/ doses

Generic Name (alphabetical)	Indication (BNF)	Dose range (Adults*)	Formulary positioning (BHFT)/Comments
Amisulpride	Acute psychotic episode in schizophrenia Schizophrenia with predominantly negative	400–800 mg daily in 2 divided doses, adjusted according to response; maximum 1.2 g per day. 50–300 mg daily.	First line – in line with NICE Guidelines, patients should be offered a choice based on side effect profiles amongst other aspects.
Aripiprazole	Schizophrenia Treatment and recurrence prevention of mania	10–15 mg once daily; usual dose 15 mg once daily (max. per dose 30 mg once daily). 15 mg once daily, increased if necessary up to 30 mg once daily.	First line – in line with NICE Guidelines, patients should be offered a choice based on side effect profiles amongst other aspects.
Flupentixol	Schizophrenia and other psychoses, particularly with apathy and withdrawal but not mania or psychomotor hyperactivity Depressive illness	Initially 3–9 mg twice daily, adjusted according to response, for debilitated patients, use elderly dose; maximum 18 mg per day. For Elderly Initially 0.75–4.5 mg twice daily, adjusted according to response Initially 1 mg once daily, dose to be taken in the morning, increased if necessary to 2 mg after 1 week, doses above 2 mg to be given in divided doses, last dose to be taken before 4 pm; discontinue if no response after 1 week at maximum dosage; maximum 3 mg per day. For Elderly Initially 500 micrograms daily, dose to be taken in the morning, then increased if necessary to 1 mg after 1 week, doses above 1 mg to be given in divided doses, last dose to be taken before 4 pm; discontinue if no	First line – in line with NICE Guidelines, patients should be offered a choice based on side effect profiles amongst other aspects.

Author	Date of production / Review Date:		
Job Title		Version	V.
Protocol Lead	[Secondary Care Specialist]	Page number	10 of 15



			Integrated Care System
		response after 1 week at	
		maximum dosage; maximum	
		1.5 mg per day.	
Haloperidol			First line – in line with NICE Guidelines, patients should be offered a choice based on side effect profiles amongst other aspects.
Lurasidone	Schizophrenia	Initially 37 mg once daily, increased if necessary up to 148 mg once daily. 18.5mg once daily with concomitant moderate CYP3A4 inhibitors (e.g. diltiazerm, erythromycin, fluconazole, verapamil)	First line – in line with NICE Guidelines, patients should be offered a choice based on side effect profiles amongst other aspects. Berkshire East: Restricted use for patients at high risk of developing
Oustioning		Maintenance doses:	metabolic syndrome. Modified release
Quetiapine	Schizophrenia Treatment of	Usual dose 300–450 mg daily in 2 divided doses, maximum 750 mg per day.	preparations are approved for use only within BHFT. GPs will not prescribe quetiapine XL
	mania in bipolar disorder	Usual dose 400–800 mg daily in 2 divided doses, maximum 800 mg per day.	
	Prevention of mania and depression in bipolar disorder	Usual dose 300 mg once daily.	
	Adjunctive treatment of major	Usual dose 150–300 mg once daily.	
	depression	For Elderly; the rate of dose titration may need to be slower and the daily dose lower in elderly patients - Initially 50 mg once daily, adjusted according to response. Adjusted in steps of 50 mg daily.	
Risperidone	Acute and chronic psychosis	Usual dose 4–6 mg daily, doses above 10 mg daily only if benefit considered to outweigh risk; maximum 16 mg per day.	First line – in line with NICE Guidelines, patients should be offered a choice based on side effect profiles amongst other
Author		Date of production / Review Date:	

Author		Date of production / Review Date:	
Job Title		Version	V.
Protocol Lead	[Secondary Care Specialist]	Page number	11 of 15



Mania Initially 2 mg once daily, then increased in steps of 1 mg daily if required; usual dose 1–6 mg daily. For Elderly; Initially 500 micrograms twice daily, then increased in steps of 500 micrograms twice daily,	aspects.
Initially 500 micrograms twice daily, then increased in steps of	
increased to 1–2 mg twice daily.	
Sulpiride Schizophrenia 200–400 mg twice daily; maximum 800 mg per day. predominantly negative symptoms	First line – in line with NICE Guidelines, patients should be offered a choice based on side effect profiles amongst other aspects.
Schizophrenia 200–400 mg twice daily; maximum 2.4 g per day. positive symptoms	·
Zuclopentixol Schizophrenia and other psychoses usual maintenance 20–50 mg daily (max. per dose 40 mg), for debilitated patients, use elderly dose. For Elderly Initially 5–15 mg daily in divided doses, increased if necessary up to 150 mg daily; usual maintenance 20–50 mg daily (max. per dose 40 mg).	First line – in line with NICE Guidelines, patients should be offered a choice based on side effect profiles amongst other aspects.

For frail and elderly patients, use half adult doses except where specified.

Author		Date of production / Review Date:	
Job Title		Version	V.
Protocol Lead	[Secondary Care Specialist]	Page number	12 of 15

Appendix 2: Management of Adverse Effects



Adverse effect	Signs and Symptoms	Management by GP
EPSE: Parkinsonism	Muscle stiffness, tremor, bradykinesia etc.	Consider prescribing procyclidine or trihexphenidyl for a week to see if symptoms improve. Not for long term use – review regularly. Refer back to Psychiatrist for consideration of dose reduction or change to a different antipsychotic with lower propensity to cause EPSE.
EPSE: Dystonia	Eyes rolling upwards (oculogyric crisis) Head and neck twisted to side (torticollis)	Medical emergency – refer to A&E Refer back to Psychiatrist for urgent review of treatment.
ExtraPyramidal Side Effects (EPSE): Akathisia	Feeling of 'inner restlessness' which can appear as; foot stamping, crossing/uncrossing legs, pacing	Refer back to Psychiatrist for consideration of dose reduction or change to a different antipsychotic with lower propensity to cause EPSE.
ExtraPyramidal Side Effects (EPSE): Tardive dyskinesia Develops after long term use and can be irreversible.	Lip smacking, tongue protrusion, choreiform hand movements, pelvic thrusting.	Refer back to Psychiatrist for consideration of dose reduction or change to a different antipsychotic with lower propensity to cause EPSE.
Hyperprolactinaemia	Raised prolactin levels, sexual dysfunction, amenorrhoea or dysmenorrhoea. Other long term side consequences include osteoporosis, increased risk of breast cancer.	Consider other causes (pregnancy, hypothyroidism, renal impairment etc.) Refer to Psychiatrist where physical causes can easily be excluded.
Neuroleptic Malignant Syndrome (NMS)	Hyperthermia, fever, sweating, muscle rigidity, autonomic instability, altered consciousness, confusion, fluctuating blood pressure, tachycardia, raised creatine kinase	Stop treatment and discuss with Psychiatrist urgently. In an emergency, send the patient to A&E.
Abnormal ECG / Cardiac disorders: QTc prolongation and arrhythmias	(presentation varies greatly)	Depending on severity of symptoms, stop treatment before contacting Psychiatrist. Discuss with Psychiatrist
Weight Gain		Offer weight management advice. If persistent and unmanageable, then refer back to Psychiatrist for treatment review.

Author		Date of production / Review Date:	
Job Title		Version	V.
Protocol Lead	[Secondary Care Specialist]	Page number	13 of 15



Handychart 1	Some of the main side effects (see BNF/ SPC for full list)					
Oral	Feeling	Stiff	Weight	Dry Mouth	Sexual	
Antipsychotic	sleepy	muscles	Gain	-	Problems	
Risperidone	•		••	•	••	
Olanzapine	•••	•	•••	•	•	
Quetiapine	•••	•	••	•	•	
Lurasidone*	•	•	0	0	0	
Amisulpride	•		•	•	•••	
Sulpiride	•		••	•	•••	
Aripiprazole	•	•	0	0	0	
Haloperidol	•	•••	••	•	•••	
Zuclopentixol	••	••	•••	••	•••	

Key:

- Most people will get this side effect (mild)
- -- Quite a few will get this side effect (moderate)
- ••• Only a few people will get this side effect (marked)
- This is very rare or not known

Reference: Extracted from Choice and Medication Handychart for Psychosis and Schizophrenia V06.14 (Link)

* Lurasidone use should be prioritised for only those patients who are at high risk of metabolic syndrome.

In studies, lurasidone appears to have a lower propensity to cause adverse metabolic side effects compared with olanzapine and quetiapine. NNH vs placebo for weight gain >/=7% from baseline was 4 for olanzapine and 9 for quetiapine XL in contrast to an NNH ranging from 43 to 150 for lurasidone (Citrome 2012).

Author			
Job Title		Version	٧.
Protocol Lead	[Secondary Care Specialist]	Page number	14 of 15

Appendix 3: Review and amendment history

	Title of Guideline	Prescribing arrangement for the management of patients transferring from Secondary Care to Primary Care Prescribing and Monitoring of Oral Antipsychotics				
			lonitoring of Oral Ant	ipsychotics		
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Version	Review Date	Reviewer	Description of	Peer review	Consultation	Date of Approval
			major change(s)			
V1	New document	Ozma Tahir	-	As above	As above	09/07/2020

Author	Ozma Tahir	Date of production:	22/07/2020
Job Title	Lead Clinical Economy and Clinical Trials Pharmacist	Review Date	30/06/2022
Protocol Lead	Dr Sanjoo Chengappa	Version	v.1.0