Cheshire and Wirral Partnership NHS
NHS Foundation Trust

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Policy for prescribing antipsychotic medication in Bipolar Disorder

Lead executive	Medical Director
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Type of document	Policy
Target audience	All clinical staff
Document purpose	The aim of this policy is to advance cost-effective, evidence-based prescribing, in line with NICE Clinical Guidance 38, within Cheshire & Wirral Partnership NHS Foundation Trust and beyond.

Document consultation		
AMH – Wirral	Yes	Jan Pye; Rashmi Parhee; Jose Ferran; Geraldine Swift; Joanne Hurley; Neal Fenna; Linda Friend; Iain Wells; June Thornton; AMH Consultants
AMH – West	Yes	Joanne Knowles; Joy Fenna; Daniel Carlson; Dave Appleton; AMH Consultants
AMH – East	Yes	Sally Sanderson; Jane Tyrer; Kate Chapman; Karen Millard; Laura Draper; Mark Grey; Nichola Spinney; Jenny Jones; AMH Consultants
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Groups / Committees	Yes	The antipsychotics in bipolar disorder T&FG
Involvement taskforce	Yes	PPI rep for MMG

Approving meeting	Medicines Management Group	25-Feb-14
Original issue date	Feb-14	
Implementation date	Feb-14	

CWP documents to be read in conjunction with	HR6	Mandatory Employee Learning (MEL) policy
	MP1	Medicines policy
	MP3	Guidance on the recommended psychotropic agents for use in pregnancy and lactation
	MP4	Lithium Policy
	MP6	Introduction of new medicines and non-formulary applications
	MP9	Policy for the initiation and maintenance of prescribing medicines for "off-label" indication (licensed medicine for unlicensed indications)
	MP10	Rapid tranquilisation policy
	MP18	High Dose Antipsychotic Therapy (HDAT)

Training requirements	No - Training requirements for this policy are in accordance with the CWP Training Needs Analysis (TNA)

Financial resource implications	No

Equality Impact Assessment (EIA)

Initial assessment	Yes/No	Comments
Does this document affect one group less or more favourably than another on the basis of:		
• Race	No	
• Ethnic origins (including gypsies and travellers)	No	
• Nationality	No	
• Gender	No	
• Culture	No	
• Religion or belief	No	
• Sexual orientation including lesbian, gay and bisexual people	No	
• Age	No	
• Disability - learning disabilities, physical disability, sensory impairment and mental health problems	No	
Is there any evidence that some groups are affected differently?	No	
If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?		
N/A		
Is the impact of the document likely to be negative?	No	
• If so can the impact be avoided?	N/A	
• What alternatives are there to achieving the document without the impact?	N/A	
• Can we reduce the impact by taking different action?	N/A	
Where an adverse or negative impact on equality group(s) has been identified during the initial screening process a full EIA assessment should be conducted.		

If you have identified a potential discriminatory impact of this procedural document, please refer it to the human resource department together with any suggestions as to the action required to avoid / reduce this impact.

For advice in respect of answering the above questions, please contact the human resource department.

Was a full impact assessment required?	No	
What is the level of impact?	Low	

Document change history

Changes made with rationale and impact on practice
1.

External references

References
1. National Institute for Health and Clinical Excellence. Bipolar disorder. The management of bipolar disorder in adults, children and adolescents, in primary and secondary care. Clinical Guidance 38.2006. www.nice.org.uk 2. Calabrese JR et al/ A randomised, double-blind, placebo-controlled trial of quetiapine in the treatment of bipolar I or bipolar 11 depression. Am J Psychiatry 2005; . 3. Thase ME et al. Efficacy of quetiapine monotherapy in bipolar I and II depression: a double-blind, placebo-controlled study (the BOLDER II study). J Clin Psychopharmacology 2006; 4. Suppes T et al. Effectiveness of the extended release formulation of quetiapine as monotherapy for the treatment of acute bipolar depression. J Affect Disord 2010; 5. Young AH et al. A double-blind, placebo-controlled study of quetiapine and lithium monotherapy in adults in the acute phase of bipolar depression (EMBOLDEN I). J Clin Psychiatry 2010; 6. McElroy SL et al. A double-blind, placebo-controlled study of quetiapine and paroxetine as monotherapy in adults with bipolar depression (EMBOLDEN II). J Clin Psychiatry 2010; 7. Goodwin GM. Evidence-based guidelines for treating bipolar disorder: revised second edition-recommendations from the British Association for Psychopharmacology. J Psychopharmacol 2009; 8. Tohen M et al. Olanzapine verses divalproex sodium for the treatment of acute mania and maintenance of remission: a 47-week study. Am J Psychiatry 2003; 9. Vieta E et al. Efficacy and safety of quetiapine in combination with lithium or divalproex for maintenance of patients with bipolar I disorder (international trial 126). J Affect Disord 2008; 10. McIntyre RS. Aripirazole for the maintenance treatment of bipolar I disorder: A review. Clin Ther 2010; 11. National Institute of Health and Clinical Excellence. Schizophrenia. Core interventions in the treatment and management of schizophrenia in adults in primary and secondary care. Clinical Guidance 82. 2009. www.nice.org.uk 12. The Psychotropic Drug Directory 2012; Stephen Bazire; HealthComm UK Ltd

Monitoring compliance with the processes outlined within this document

Please state how this document will be monitored. If the document is linked to the NHSLA accreditation process, please complete the monitoring section below.	An annual audit of clinicians' prescribing of antipsychotic medicines in bipolar disorder across CWP and Primary Care footprint in accordance with the Policy parameters. The audit will be worked into the audit cycle of the MMG and the CCGs.

Content

1. Introduction

The aim of this policy is to advance evidenced-based, cost-effective prescribing within Cheshire & Wirral Partnership NHS Foundation Trust (CWP) and beyond. The scope of this policy is for the use of antipsychotics in bipolar disorder as part of mania, depression and maintenance treatment. The policy is not intended to be a guideline for the treatment of bipolar disorder as a whole and clinicians are referred to NICE Clinical Guidance 38: The management of bipolar disorder in adults, children and adolescents in primary and secondary care.

In May 2012, a multidisciplinary Antipsychotic Use in Bipolar Disorder Task & Finish Group was set up by the CWP Medicines Management Group. This was carried out in conjunction with the Trust's three Primary Care Trust (PCT) partner organisations.

The focus of this group was to review and promote cost-effective, evidenced-based prescribing of antipsychotic medication within the CWP footprint for Bipolar Disorder, whilst ensuring that higher cost drugs are available but used more efficiently and appropriately.

The treatment of bipolar disorder is based primarily on psychotropic medication to reduce the severity of symptoms, stabilise mood and prevent relapse. Antipsychotic medications may have a role in such treatment. This policy makes recommendations as to which antipsychotic should be used in the treatment of the different phases of the illness. Individual variation in response to medication will often determine the choice of drug, as will the side effects and potential harms associated with each drug (see appendix 2).

Note: Risperidone long-acting injection (LAI) is not licensed for use in bipolar disorder and so is not within the scope of this guideline. Asenapine was licensed for bipolar mania in 2012 but should not be initiated as it is currently non-formulary within the trust.

2. Mania / hypomania

The drug treatment of an acute manic or hypomanic episode depends on the severity of symptoms and whether patients are currently taking antimanic drugs. Clinicians should be guided by current medication doses and previous response.

If a patient develops acute mania when not taking antimanic medication, treatment options include starting an antipsychotic, valproate or lithium. According to NICE guidelines when making the choice, prescribers should take into account preferences for future prophylactic use and the side effect profile, and consider prescribing an antipsychotic if there are severe manic symptoms or marked behavioural disturbance as part of the syndrome of mania[1]. Information on prescribing and monitoring of lithium is outside the scope of this guidance but may be found in MP4 Lithium Policy

The only antipsychotics licensed for the treatment of bipolar mania in the UK are risperidone, olanzapine, quetiapine, aripiprazole and asenapine.

When treating acute mania with antipsychotics in adults the preferred choices are oral olanzapine, quetiapine immediate release (IR) or risperidone and the following should be taken into account:

- Individual risk factors for side effects;
- The need to titrate treatment at the lower end of the therapeutic dose range recommended in the summary of product characteristics and titrate according to response;
- That if an antipsychotic alone proves inadequate augmenting it with valproate or lithium should be considered.

Aripiprazole is licensed for treatment of mania in adolescents aged 13-18 years and is recommended by NICE TA292 as an option for treating moderate to severe manic episodes in adolescents with bipolar I disorder. It should be considered as a treatment option alongside olanzapine, risperidone and quetiapine taking the factors listed above into account.

To facilitate more efficient use of resources, initiation of aripiprazole for adults and quetiapine prolonged release formulation (XL) for all ages will only be by non-formulary application, as per section 5 of this policy. Asenapine was licensed for bipolar mania in 2012 but should not be initiated as it is currently non-formulary within this trust.

3. Bipolar depression

In the UK, quetiapine is licensed for the treatment of severe depressive episodes in bipolar disorder, and for the prevention of recurrence if symptoms have responded acutely.

In the treatment of bipolar depression, NICE recommends the initial use of a selective serotonin re-uptake inhibitor (SSRI) in addition to an antimanic drug or quetiapine (assuming an antipsychotic is not already prescribed)[1].

Five large randomised controlled trials have demonstrated clear efficacy for doses of Quetiapine between 300mg and 600mg daily as monotherapy in bipolar I and bipolar II depression[2-6]. Quetiapine prevents relapse into depression and mania so is probably the drug of choice in bipolar depression[7]. It appears not to be associated with a switch to mania.

Therefore quetiapine immediate release (IR) is the antipsychotic of first choice in bipolar depression as it has an evidence base, and also has antimanic and prophylactic effects. If quetiapine IR has been effective in the acute stage then it can be continued as maintenance treatment. If quetiapine prolonged release formulation (XL) is required, initiation will be by non formulary application, as per section 5 of this policy.

4. Prophylaxis and maintenance

In the UK olanzapine, quetiapine and aripiprazole are the antipsychotics licensed for prophylaxis of bipolar disorder. NICE guidelines recommend the use of olanzapine first line[1], however there is evidence to support the efficacy of olanzapine[8], quetiapine[9], and aripirazole[10].

To facilitate the more efficient use of resources, the initiation of aripiprazole and quetiapine XL formulation is only by application using section 5 of this policy.

5. Named-patient prescribing of oral aripiprazole and quetiapine XL

5.1 Patients currently prescribed oral aripiprazole or quetiapine XL

Patients within CWP currently prescribed one of these medications will continue with their current treatment. However when treatment is reviewed, and a switch is indicated (for example, due to relapse, or a period of non-concordance), the preferred formulary choices within this policy should be actively considered.

5.2 Patients requiring initiation with oral aripiprazole or quetiapine XL

If a clinician believes there are extenuating circumstances as to why a patient cannot have an alternative antipsychotic or quetiapine IR formulation, but requires a named-patient medication, then an application must be made to the Chair of the Medicines Management Group and Secretary to the Chair of the Medicines Management Group. The letter should include a full clinical history (including diagnosis), response to previous medications and rationale for the request of named-patient medication.

It should be noted that the only evidence-based doses of aripiprazole are 10 and 15mg daily. Doses above 15mg require a second non-formulary request in the same manner stated above. Higher doses should only be considered for a time-limited period and response rated using an appropriate rating scale. If no additional benefit is obtained, the dose should be reduced back to 10 or 15mg daily.

5.3 Patients under 18 requiring initiation with oral aripiprazole or quetiapine XL

If a clinician wishes to prescribe Quetiapine XL for a patient aged under 18 then an application must be made to MMG as in point 5.2 above.

As aripiprazole is recommended by NICE TA292 as a treatment option for under 18's, it is exempt from the named-patient request status and may be prescribed in this patient group without a named patient application.

6. Shared-care responsibilities

6.1 Responsibilities of the consultant

Perform mental health assessment prior to starting antipsychotic medication, to confirm indication for treatment.

Perform and assess baseline tests, before or as soon as possible within the first four weeks of treatment dependent upon clinical need.

These may include:

- Weight, height (to calculate Body Mass Index), waist measurement;
- Fasting glucose or random if not possible;
- Fasting lipid screen or random if not possible;
- BP, pulse;
- ECG if indicated:
    - Patient on drugs that could prolong QT interval such as tricyclic antidepressants, quinine;
    - Patient has a history of cardiac disease;
    - Patient is an inpatient;
    - It is a recommendation in the SPC of the antipsychotic medication.

- FBC, U&Es, LFTs, CK, Bone Profile, Prolactin (see appendix 4), TFTs. Consult local laboratory for reference ranges.

Communication between Secondary and Primary Care should detail:

- Investigations ordered and results;
- Medication(s) stopped/prescribed and/or changes made, including dose, frequency, monitoring requirements etc;
- Indication for medication, including rationale and patient consent for off-label use;
- Whether the antipsychotic is intended for long term use;
- If the antipsychotic medication is a named-patient medication (see section 5, above), a statement should be included that approval for use has been sought and granted by the Chair of the Medicines Management Group (MMG);
- Follow up required, including care co-ordinator details and management plan.

Once the dose of the antipsychotic medication is stable, invite the Primary Care prescriber to continue the prescribing by way of a letter.

6.2 Responsibilities of General Practitioner (GP)

To provide regular prescriptions for antipsychotic medications as per request after transfer of prescribing from Secondary Care.

To be aware of the increased risk of diabetes, cardiovascular disease and hyperlipidaemia, in patients who are receiving regular antipsychotics.

To monitor the physical health of the patient at least once a year. Attention should be given to cardiovascular disease risk assessment as described in 'Lipid modification' (NICE clinical guideline 67) and the development of diabetes. NICE clinical guideline 38 recommends that the results of the annual review should be given to the service user and the healthcare professionals in Primary and Secondary care (including whether the service user refused any tests)[11].

To inform Secondary Care of any physical health problems or deterioration of mental state, at the earliest opportunity. Prescribing responsibility may need to be transferred back to Secondary Care during these times.

To liaise with Secondary Care if patient suffers any adverse reaction.

7. Information for patients

There are several sources of information available for patients. The Choice & Medication website (accessed here choiceandmedication) contains patient information for the majority of psychotropic medication, including antipsychotics and other medicines used in the treatment of bipolar disorder. CWP staff are able to print off leaflets, as requested.

8. Cautions

There are several cautions for the use of antipsychotic medication, such as use in those patients with pre-existing cardiovascular disease or epilepsy. For further guidance, the relevant section of the BNF and the Summary of Product Characteristics (SPC) for the specific medicine should be consulted.

Particular attention should be paid to the use of antipsychotic medication in specific patient groups, such as older adults.

9. Interactions

A number of common interactions with antipsychotics can be found in appendix 2.
Caution should be exercised and extra monitoring undertaken, if any of these medications are co-prescribed with antipsychotics.

The latest edition of the BNF or the local Mental Health Pharmacist should be consulted for further details regarding interactions.

10. Prescribing antipsychotic medication in patients with pre-existing medical conditions

In appendix 3, an indication of the level of risk for a particular antipsychotic when used with a given pre-existing medical condition can be seen.

Note, this table should be used as a guide (current time valid) and more detailed up to date information can be found in the Psychotropic Drug Directory[12] or from your local Mental Health Pharmacist.

11. Pregnancy and lactation

When prescribing for patients who are pregnant or planning a pregnancy please refer to the CWP policy MP3 Guidance on the Recommended Psychotropic Agents for use in Pregnancy and Lactation and the Perinatal Pathway found on CWP intranet

12. Duties and responsibilities

12.1 Medical Director Compliance Quality and Regulation

Has the responsibility of overseeing the review of updating this policy in line with national guidance and changes in clinical practice.

12.2 Chair of medicines management group

It is the responsibility of the chair to ensure that the minutes of the meetings reflect the approval process and that all reviews of the policy are timetabled within the business cycle.

12.3 Author(s)

Responsibility to seek consultation on the policy and any updates, and then to seek approval of the policy via the appropriate trust channels. Once approved, ensuring that the policy has been disseminated appropriately and raising staff awareness of the policy.

12.4 Line managers

Have responsibility to cascade information on the revised policy to all staff that they manage and to ensure that any training required on the policy is included in staff's personal development plan and clinical supervision.

12.5 Trust Staff

All Trust Staff working in a clinical environment must be familiar with the policy and any subsequent updates. There is no specific training attached to this policy beyond knowledge of the national guidance and knowledge of the medicines identified within the policy. It is the responsibility of staff to keep up to date with current practice through their individual PDPs in this area of practice.

Appendix 1 - Summary of Antipsychotic Medication Used in Bipolar Disorder

Medicine	Usual dose (per day)	Titration required	Formulations	Side effects					Cost (£/28 days)
				Sedation	Muscle stiffness	Weight Gain	Dry mouth etc	Sexual problems	
First line antipsychotic medications to be used in the treatment of bipolar **Mania/ Hypomania**:									
Olanzapine	10 – 20mg	No	Tablets - Oro-dispersible tablets (generic)	• • •	•	• • •	•	•	£26.22 - £47.67
Risperidone	2 – 6mg	Yes	Tablets - Oro-dispersible tablets Liquid	•	• •	• •	•	• •	£0.97 - £26.11
Quetiapine IR	Around 600mg	Yes	Immediate Release (IR) tablets	• • •	•	• •	•	•	£219.42
Note: Oro-dispersible is the generic term used to describe tablets which dissolve in the mouth. The use of other terms such as Velotab® may result in brand specific dispensing leading to higher drug costs. For Olanzapine oro-dispersible generic tablets are recommended 1st line when a soluble tablet is required. Velotabs are non-formulary.									
Named-patient request only (for patients under 18 named patient request not required for aripiprazole):									
Aripiprazole	10 – 30mg	No	Tablets - Oro-dispersible tablets Liquid	•	•	o	o	o	£95.74 - £191.47
Quetiapine XL	Around 600mg	Yes	Extended release tablets	• • •	•	• •	•	•	£340.00
First line antipsychotic medications to be used in the treatment of bipolar **Depression**:									
Quetiapine IR	Around 600mg	Yes	Immediate Release (IR) tablets	• • •	•	• •	•	•	£219.42
Named-patient request only:									
Quetiapine XL	Around 600mg	Yes	Extended release tablets	• • •	•	• •	•	•	£340.00
First line antipsychotic medications to be used in the treatment of bipolar **Prophylaxis / maintenance**:									
Olanzapine	10 – 20mg	No	Tablets Oro-dispersible tablets	• • •	•	• • •	•	•	£26.22 - £47.67
Quetiapine IR	Around 600mg	Yes	Immediate Release (IR) tablets	• • •	•	• •	•	•	£219.42
Named-patient request only (for patients under 18 named patient request not required for aripiprazole):									
Aripiprazole	10 – 30mg	No	Tablets Oro-dispersible tablets / Liquid	•	•	o	o	o	£95.74 - £191.47
Quetiapine XL	Around 600mg	Yes	Extended release (XL) tablets	• • •	•	• •	•	•	£340.00

Prices taken from BNF65 - March 2013

Key:

• = Only a few people will get this side effect
• • = Quite a few people will get this side effect
• • • = Most people will get this side effect
o = side effect not reported

Table adapted from www.choiceandmedication.org

Appendix 2 - Common interactions with Antipsychotic Medication*

Interacting drug class	Consequences
Angiotensin-converting enzyme (ACE) inhibitors or calcium channel blockers	Risk of postural hypotension
Antiarrhythmic drugs	Increased risk of ventricular arrhythmia with antiarrhythmic drugs that prolong the QT interval such as amiodarone.
Antibacterials	Erythromycin possibly increases plasma concentration of clozapine. Ciprofloxacin increases plasma concentration of clozapine and possibly olanzapine. Plasma concentration of quetiapine possibly increased by macrolides (e.g. erythromycin).
Antidepressants	Increased risk of arrhythmias with tricyclic antidepressants. Selective serotonin re-uptake inhibitors (SSRIs) and venlafaxine increase the plasma concentration of clozapine. Fluoxetine increases the plasma concentration of haloperidol.
Antiepileptics	The threshold for convulsions is lowered. Carbamazepine reduces the plasma concentration of clozapine, haloperidol, olanzapine and risperidone. Phenytoin reduces the plasma concentration of clozapine and quetiapine. The risk of neutropenia is increased if olanzapine is given with sodium valproate.
Antivirals	Plasma concentration of clozapine possibly increased by ritonavir (avoid concomitant use) and possibly by amprenavir. Plasma concentration of olanzapine reduced by ritonavir (may need to increase dose). Plasma concentration of aripiprazole possibly reduced by efavirenz and nevirapine, metabolism of aripiprazole possibly inhibited by amprenavir, atazanavir, indinavir, lopinavir, nelfinavir, ritonavir, and saquinavir (reduce dose of aripiprazole) Plasma concentrations of antipsychotics possibly increased by ritonavir.
Lithium	Increasing lithium levels has a direct neurotoxic effect, including increased risk of neuroleptic malignant syndrome (NMS), particularly with clozapine, haloperidol and phenothiazines

* Table complied using the British National Formulary (BNF) 65, BMJ Group and Pharmaceutical Press 2013.

Appendix 3 - Antipsychotic Selection in Patients with Pre-existing Medical Conditions*

	Level of Risk of Antipsychotic Medication		
	Low	**Moderate**	**High**
Cardiovascular disease	Quetiapine	Aripiprazole Olanzapine Risperidone	--
Diabetes	Aripiprazole Risperidone	Quetiapine	Olanzapine
Epilepsy	Aripiprazole Risperidone	Olanzapine Quetiapine	--
Glaucoma (narrow-angle)	Risperidone	Aripiprazole	Olanzapine
Hepatic impairment	Aripiprazole	Olanzapine Quetiapine Risperidone	--
Renal impairment	--	Aripiprazole Olanzapine Quetiapine	Risperidone

* Table adapted from Stephen Bazire's Psychotropic Drug Directory 2012, HealthComm UK Ltd

Appendix 4 - Hyperprolactinaemia

Dopamine receptor blockade in the tuberoinfundibular pathway can lead to increased levels of prolactin. All antipsychotics have the propensity to cause this, however some do not increase prolactin levels above the normal range at standard doses. These antipsychotic medications are: **aripiprazole, clozapine, olanzapine and quetiapine.** The degree of prolactin elevation is likely to be dose related. While the propensity for antipsychotic drugs to affect prolactin varies between agents, the extent to which an individual will be affected may be difficult to determine before treatment. Therefore, good practice would dictate that prolactin levels should be checked at least annually, and more frequently if indicated (e.g. if sexual dysfunction reported).

Hyperprolactinaemia often presents asymptomatically and there is evidence to suggest it does not affect quality of life. In women, hyperprolactinaemia may be associated with galactorrhoea, amenorrhoea, gynaecomastia, and decreased libido. In men, hyperprolactinaemia can cause reduced serum testosterone levels leading to decreased libido, erectile dysfunction, impotence, infertility, gynaecomastia, and rarely galactorrhoea. Sustained hyperprolactinaemia may lead to decreased bone density in both female and male patients. There is also some evidence to suggest hyperprolactinaemia may be associated with an increased risk of breast cancer, although the evidence is too limited to be conclusive.

Reference ranges for prolactin levels:

	Prolactin level	
	ng/ml	**mIU/L**
Men	0 - 20	0 - 424
Women	0 - 25	0 - 530
Re-test if prolactin concentration:	25 – 118	530 – 2500
Refer to rule out prolactinoma if prolactin concentration:	> 118	> 2500

There are various strategies that can be employed in treating hyperprolactinaemia, and it may be appropriate to refer back to Secondary Care (mental health) and possibly to endocrinology to rule out the risk of endocrine tumors.

Treatment options include:

- Decreasing the dose of the antipsychotic medication;
- Changing to a non-prolactin elevating antipsychotic medication;
- The addition of a dopamine agonist, such as bromocriptine or cabergoline. **This is not normally a first-line strategy**. Caution must be exercised due to an increased risk of relapse (this is usually on the advice of the endocrinologist).

Reference: The Maudsley Prescribing Guidelines 11th Edition (2012); Taylor, Patton and Kapur; Informa