# SHARED CARE GUIDELINE

Pennine Care NHS
NHS Foundation Trust

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| **Title: Shared Care Guideline for the prescribing and monitoring of Antipsychotics for the treatment of Bipolar disorder in children and adolescents.** | |
| **Scope:**<br>Pennine Care NHS Foundation Trust<br>To support an individualised care pathway where this has been previously agreed with the GP only | **Version:**<br><br>**Version 1** |
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| **Author(s)/Originator(s)** | Pennine Care NHS Foundation Trust |
| **To be read in conjunction with the following documents:** | BNF -current edition<br>BNF for children -current edition<br>Summary of Product Characteristics (SPC)<br>Pharmaceutical company's patient information leaflet (PIL)<br>**Pennine Care CL 16** The Prescribing, Supply and use of Unlicensed Medicines<br>**Pennine Care CL17** The use of Licensed Medicines outside the conditions of their Product Licence |
| **Authorised by:** | **Drugs and Therapeutics Committee** |
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| **Review Date:** | **19 April 2016** |

## 1. Scope

Pennine Care NHS Foundation Trust
To support an individualised care pathway where this has been previously agreed with the GP only

## 2. Introduction

This shared care guideline covers prescribing antipsychotics for Bipolar disorder in children and adolescents for licensed indications, and for recommended/ accepted off-label prescribing. Like many paediatric medicines, some uses of antipsychotics in this age group are with informed use of off-label prescribing

In 2000, the Royal College of Paediatrics and Child Health issued a policy statement on the use of unlicensed medicines or the use of licensed medicines for unlicensed applications, in children and young people. This states clearly that such use is necessary in paediatric practice and that doctors are legally allowed to prescribe unlicensed medicines where there are

no suitable alternatives and where the use is justified by a responsible body of professional opinion [1].

The SCG recognises there are differences in commissioning of Child and Adolescent Mental Health Services across the Trust for 16 to 18 year olds and that there are differences in the practice of prescribing and supervision for 16 to 18 year olds by working age adult psychiatrists.

## 3. Supporting information

NICE and the National Collaborating Centre for Mental Health published guidance on the management of bipolar disorder in adults, children and adolescents in primary and secondary care (CG 38) in 2006.
This guidance is currently being reviewed partly due to the availability of new evidence and trial data showing that the combination of a second generation antipsychotic (or atypical antipsychotic) with a mood stabiliser is significantly more effective than a mood stabiliser on its own in the treatment of acute mania. [2]

Many randomised controlled trials, open label trials and case studies have demonstrated the effectiveness of the second generation antipsychotics; aripiprazole, olanzapine, quetiapine and risperidone as adjuncts and for monotherapy in the management of Bipolar Disorder. [3-7]

Aripiprazole is licensed in the USA for acute treatment of manic or mixed episodes of Bipolar I Disorder for monotherapy or as an adjunct, in patients aged 10 – 17 yrs. NICE are currently developing a technology appraisal for the use of aripiprazole in the treatment and prevention of acute manic and mixed episodes of Bipolar Disorder in children and adolescents. This is due in February 2013.

## 4. Prescribing and monitoring

4.1 Prescribing
Summary of Licensed Indications, Formulations and Dosage

| Drug and Licensing | BNFc or NICE recommendation | Formulations | Dose range (daily) |
|---|---|---|---|
| Aripiprazole<br><br>Unlicensed in ≤18 years<br><br>Licensed in ≥18 yrs for:<br>-Treatment of moderate to severe manic episodes in Bipolar I Disorder<br>-Prevention of a new manic episode in patients who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment | NICE clinical guideline 38, Bipolar Disorder | Tablets<br>Oro-dispersible tablets<br>Liquid | 2-20mg¥<br><br>13-18yrs:<br>5mg-15mg*<br><br>Max. 30mg |
| Olanzapine<br><br>Unlicensed in ≤18yrs<br><br>Licensed in ≥18 yrs for:<br>-Moderate to severe manic episode<br>-Preventing recurrence in bipolar disorder in patient who have responded to olanzapine | NICE clinical guideline 38, Bipolar Disorder | Tablets<br>Oro-dispersible tablets | 2.5mg-20mg¥<br><br>12-18yrs:<br>5mg-20mg*<br><br>Use lowest maintenance dose |
| Quetiapine<br><br>Unlicensed in ≤18yrs<br><br>Licensed in ≥18 yrs for:<br>-Manic episodes associated with bipolar disorder<br>-Major depressive episodes in bipolar disorder<br>-Preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment. | NICE clinical guideline 38, Bipolar Disorder | Tablets<br>Slow-release tablets | 50mg initially then titrate ¥<br><br>12-18yrs:<br>100mg-600mg *<br><br>Dose adjusted in steps of no greater than 100mg daily.<br><br>Usual dose 400-600mg daily. |
| Risperidone<br><br>Unlicensed in ≤18yrs<br><br>Licensed in ≥18 yrs for: moderate to severe manic episodes associated with bipolar disorders | NICE clinical guideline 38, Bipolar Disorder | Tablets<br>Oro-dispersible tablets<br>Oral liquid | 0.5mg-6mg¥<br><br>12-18yrs:<br>2-6mg*<br>Max. 16 mg |

* BNF for Children recommended doses.
¥ Doses used in reported trials

4.2 Monitoring

There are concerns that children and young people are more sensitive than adults to the potential adverse effects of antipsychotics, including weight gain, metabolic effects and movement disorders.

The Specialist Team will monitor response to treatment, and adverse effects. This includes 3-monthly weight measurements, six monthly blood glucose levels measurements, and baseline and annual cholesterol and triglycerides checks. Suitable action will be taken if these give cause for concern and will be communicated to the GP.

The GP should refer any queries regarding treatment or adverse effects to the Specialist Team.

## 5. Regimen Management

a) Aspects of care for which the Specialist Team is responsible. The Specialist Team includes Child and Adolescent Psychiatrist, Paediatrician, or nominated Advanced Practitioner/ Non Medical Prescriber (in agreement with their medical supervisor)

- Direct assessment or supervision of specialist team assessment, evaluation of prior treatment, and rationalisation of treatment.
- Informing patient/ carer of diagnosis, care plan, treatment including side effects and use of unlicensed product. Use of Patient Information Leaflets (PILs), user-friendly information leaflets for children/ adolescents.
- Treatment decisions should be shared between patient, carer and the Specialist.
- Informing young person/ carers of the latest regulatory advice.
- Ascertaining patient/ family's commitment to safe storage and handling of medication.
- Asking General Practitioners (GP) if they are willing to participate in shared care.
- Initiation and titration of medication to a suitable dose or provide instructions/directions to the GP for initiation and/or titration of medication to a suitable dose where this has been agreed.
- Written correspondence to GP from Specialist Team, summarising progress and recommendations for continued treatment.
- Ensure clear arrangements for GP back up, advice and support.

- To inform young person/ carer of the risk of physical side effects, particularly around initiation of treatment.
- Monitoring response to treatment, and adverse effects.
- Ensuring concurrent psychological therapy is offered.
- Promoting access to any appropriate supporting therapies, carer education, and appropriate school liaison.
- Minimum 6 monthly Specialist review appointments once treatment is established.
- Reporting suspected adverse events to the GP and the MHRA via the Yellow Card scheme to www.mhra.gov.uk/yellowcard
- Discontinuation of treatment, (or transfer if appropriate).

Aspects of care for which the GP is responsible:

- Replying to requests for shared care as soon as possible.
- Initiation and titration of medication where there is agreement/ Continued prescribing of medication in the community under guidance of Consultant/ Specialist Team
- To undertake appropriate investigations, during treatment if requested by the Consultant.
- Refer to the Consultant/Specialist Team for queries regarding treatment/side effects, and concerns about compliance or suspected drug misuse.
- Ensure compatibility of medication with concomitant prescribed medication.
- Stopping treatment on the advice of the Consultant/Specialist team.
- Continuation without specialist review is not recommended.
- Reporting suspected adverse events to the Specialist team and the MHRA via the Yellow Card scheme to www.mhra.gov.uk/yellowcard

## 6. Summary of cautions, contra indications, side effects & interactions

Please refer to the current edition of the BNF and BNF for Children and SPCs of the individual drugs for the latest list of contraindication, cautions, side effects and interactions.

**Contraindications –**

Comatose states

CNS depression

Phaeochromocytoma

**Cautions –**

Cardiovascular disease

Parkinson's disease

Epilepsy

Depression

Myasthenia Gravis

Prostatic hypertrophy

A susceptibility to angle-closure glaucoma.

Severe respiratory disease

History of jaundice

History of blood dyscrasias

**Side Effects –**

Extrapyramidal symptoms - parkinsonian symptoms, dystonia (abnormal face and body movements) and dyskinesia, akathisia, tardive dyskinesia (rhythmic, involuntary movements of tongue, face, and jaw).

Hyperprolactinaemia - sexual dysfunction, reduced bone mineral density, menstrual disturbances, breast enlargement, and galactorrhoea.

Cardiovascular – as tachycardia, arrhythmias and hypotension.

Hyperglycaemia and sometimes diabetes can occur with antipsychotic drugs, particularly clozapine, olanzapine, quetiapine, and risperidone.

All antipsychotic drugs may cause weight gain, but the risk and extent varies. Clozapine and olanzapine commonly cause weight gain.

Neuroleptic malignant syndrome (hyperthermia, fluctuating level of consciousness, muscle rigidity, and autonomic dysfunction with pallor, tachycardia, labile blood pressure, sweating, and urinary incontinence) is a rare but potentially fatal side-effect of all antipsychotic drugs.

**Interactions**

General anaesthetics

Anti-arrythmics

Tricyclic antidepressants

Antiepileptics

Atomoxetine

Methadone

Ritonavir

Please refer to the current edition of the BNF and BNF for Children and SPCs of the individual drugs for the latest list of contraindication, cautions, side effects and interactions.

## 7. Back-up care available to GP from Hospital, including emergency contact procedures and help line numbers.

Written correspondence following Specialist Team appointments, specifically detailing the next review date and any dose adjustments.

Telephone advice/ information from the Specialist Team during office hours, and plans for earlier review by team if necessary.

Dr [insert text here]_____

Contact number: [insert text here] _____

Hospital: [insert text here]_____

Out of hours on call/ emergency mental health service contactable through hospital switchboards.

## 8. Statement of Agreement between GP and Specialist Team.

This document outlines the suggested care pathway of the named patient. If you are unable to agree to the sharing of care and prescribing the suggested medication, please make this known to the Consultant within 14 days stating the nature of your concern.

## 9. Written information provided to patient

- Pennine Care NHS Foundation Trust Patient Information Leaflet
- Patient information leaflet

## 10. Supporting references


1. Joint Royal College of Paediatrics and Child Health/Neonatal and Paediatric Pharmacists Group Standing Committee on Medicines, 2000
2. National Institute for Health and Clinical Excellence, NICE clinical guideline 38, Bipolar Disorder, March 2006

3. Carson WH., et al. Acute efficacy of aripiprazole for the treatment of bipolar disorder in paediatric patients. *Schizophrenia Research* 2008; 98:42.

4. Doey T. Aripiprazole in pediatric psychosis and bipolar disorder: A clinical review. Journal of Affective Disorders. 2012;138,S15-S21

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7. Tohen M., et al. Olanzapine versus placebo in the treatment of adolescents with bipolar mania. *Americal Journal of Psychiatry*. 2007;164(10):1547-1556

8. BNF for Children 2011-2012 and BNF 63 March 2012

9. Maudsley Prescribing Guidelines, 10th Edition, Informa Healthcare, 2009

10. Summary of product characteristics (SPC) for recommended drugs. www.medicines.org.uk

11. James AC. Prescribing antipsychotics for children and adolescents. *Advances in psychiatric treatment* 2010; 16:63-75

12. Liu HY., et al. Pharmacologic Treatments for Pediatric Bipolar Disorder: A Review and Meta-Analysis. Journal of the American Academy of Child & Adolescent Psychiatry. 2011;50(8):749-762.e39