

SHARED CARE GUIDELINE

Shared Care Guideline for the prescribing and monitoring of antipsychotics for the treatment of Neurodevelopmental Disorders in children and adolescents.

Scope: Pennine Care NHS Foundation Trust To support an individualised care pathway where this has been previously agreed with the GP <u>only</u>	Version 1
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Replaces:	
Author(s)/Originator(s)	Pennine Care NHS Foundation Trust
To be read in conjunction with the following documents:	BNF 63 March 2012 BNF for children 2011-2012 Summary of Product Characteristics (SPC) Pharmaceutical company's patient information leaflet (PIL) Pennine Care CL 16 The Prescribing, Supply and use of Unlicensed Medicines Pennine Care CL17 The use of Licensed Medicines outside the conditions of their Product Licence
Authorised by:	Drugs and Therapeutics Committee Pennine Care NHS Foundation Trust
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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 of antipsychotics for the management of neurodevelopmental disorders in children and adolescents for licensed indications, and for recommended/ accepted off-label prescribing. Neurodevelopmental disorders commonly treated by the Pennine Care NHS Foundation Trust CAMHS Specialist team include autistic spectrum disorders (ASD), attention deficit hyperactivity disorder (ADHD) and learning disabilities

(LD). 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

Many studies have investigated the effectiveness and safety of pharmacological management of children and adolescents on the autistic spectrum. The antipsychotics commonly used in practice and that have been studied are aripiprazole, haloperidol, olanzapine, risperidone and quetiapine.

Small scale randomised controlled trials (RCTs) show significant reduction in sensory motor and language subscale scores on the Ritvo-Freeman Real Life rating scale and an improvement in divided attention in young children with autism prescribed risperidone.

Research on Paediatric Psychopharmacology Austim Network in the US conducted a study which looked at use of risperidone and its effects on the core symptom domains of autism. Results showed improvements in the areas of sensory motor behaviours, affectual reactions and sensory responses in children with autism. Risperidone is now approved in the US for the treatment of irritability and concomitant aggressive behaviours in autism. [2,3,4,5]

Similarly other RCTs, open label trials and case studies looking at treatment with aripiprazole, olanzapine and quetiapine have shown improvements in aggression and irritability, hyperactivity and inattention, and self-injury. [2,3,6,7]

Currently there is no NICE guidance on the management or treatment of autism spectrum disorder in children and adolescents. New NICE guidance – Autism – management of autism in children and young people is expected to be published in November 2013.

4. Prescribing and monitoring

4.1 Prescribing

Summary of Licensed Indications, Formulations and Dosage

Drug	Licensing	Formulations	Dose range (daily)
Aripiprazole	Unlicensed	Tablets Oro-dispersible tablets Oral solution	2.5mg-15mg*
Haloperidol	Unlicensed	Tablets Oral liquid	0.25mg-4mg*
Olanzapine	Unlicensed	Tablets Oro-dispers. tablets	5mg-20mg*
Quetiapine	Unlicensed	Tablets Slow-release tablets	25mg-750mg*
Risperidone	Unlicensed	Tablets Oro-dispers. tablets Oral liquid	0.1-3.5mg* - ASD 1mg-3mg^ - LD

[2,3, 8-11]

* Doses used in reported trials. [2]

^ Doses used in reported trials. [3]

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 3-6 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 is responsible. The term Specialist includes Child and Adolescent Psychiatrist, Paediatrician, or nominated Advanced Practitioner/ Non Medical Prescriber (in agreement with their medical supervisor)
- Informing patient/ carer of diagnosis, care plan, treatment including side effects and use of unlicensed product.
 - Treatment decisions being shared between the patient, parents and the Consultant.
 - Informing the patient/ parents of the latest regulatory advice.
 - Ascertaining patient/ family's commitment to safe storage and handling of medication.
 - Asking the General Practitioner (GP) if they would be 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 titration of medication to a suitable dose where agreed
 - Written correspondence to GP from summarising progress and recommendations for continued treatment.
 - Ensure clear arrangements for GP back up, advice and support.
 - Monitoring response to treatment and adverse effects. Three to six monthly weight measurement, six monthly blood glucose, cholesterol and triglycerides, with suitable action being taken if these give cause for concern.
 - Promoting access to any appropriate supporting therapies, carer education, and appropriate school liaison as appropriate
 - Minimum 6 monthly review appointments 'once established on treatment'
 - Reporting suspected adverse events to the GP and the MHRA via the Yellow Card scheme to www.mhra.gov.uk/yellowcard
 - Discontinuation of treatment

- b) Conditions of assuming responsibility by the GP:
- Communication of satisfactory baseline physical checks.
 - Satisfactory directions/instructions for initiation or titration to optimum dosage and response to treatment.

	Consultant	Usual GP
6 monthly follow up of progress and response to medication	Yes	N/A
If changes noted	Amend dose accordingly	Refer to Consultant

- c) 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 agreed / Continued prescribing of medication in the community under guidance of Consultant/ Specialist Team.
 - To undertake appropriate tests, during treatment if requested to do so 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 antipsychotic with concomitant prescribed medication.
 - Stopping treatment on the advice of the Consultant/Specialist team.
 - Continuation without specialist review is not recommended.
 - Reporting noted adverse events to the Consultant/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 Summary of Product Characteristics (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 Consultant/ Specialist Team appointments, specifically detailing the next review date and any dose adjustments.

Telephone advice/ information from the Consultant / 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 Consultant.

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. References

1. Joint Royal College of Paediatrics and Child Health/Neonatal and Paediatric Pharmacists Group Standing Committee on Medicines, 2000.
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3. Chavez B., *et al.* Atypical antipsychotics in children with pervasive developmental disorders. *Paediatric Drugs.* 2007; 9 (4):249-266
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5. McDougle C., *et al.* Risperidone for the core symptom domains of autism: results from the study by the Autism Network of the Research Units on Paediatric Psychopharmacology. *American Journal of Psychiatry* 2005; 162:1142-1148
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7. 11. Owen, R., et al., Aripiprazole in the treatment of irritability in children and adolescents with autistic disorder, *Paediatrics*, 124/6 1533-1540, 2009
8. BNF for Children 2011-2012
9. BNF 63 September 2012
10. Summary of product characteristics (SPC) for recommended drugs. www.medicines.org.uk.

11. James AC. Prescribing antipsychotics for children and adolescents.
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