**GREATER MANCHESTER INTERFACE PRESCRIBING GROUP**

On behalf of the
GREATER MANCHESTER MEDICINES MANAGEMENT GROUP

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| **SHARED CARE GUIDELINE: METHYLPHENIDATE AND DEXAMFETAMINE FOR CHILDHOOD AND ADOLESCENT ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)** | **Reference Number**<br>Version 4 |
| **Scope:**<br>Pennine Care NHS Foundation Trust<br>NHS Bury<br>NHS Oldham<br>NHS Heywood, Middleton & Rochdale<br>NHS Stockport<br>NHS Tameside & Glossop | **Classification**<br>SHARED CARE GUIDELINE |

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| **Issue date:** | 16 February 2011 | |
| **Author(s)/Originator(s):** | Pennine Care NHS Foundation Trust | |
| **To be read in conjunction with the following documents** | British National Formulary (BNF) and BNF for Children<br>Summary of Product Characteristics (SPC)<br>Pharmaceutical company's Patient Information Leaflet (PIL) | |
| **Authorised by** | Drugs & Therapeutics Committee | 4 February 2011 |
| **Review Date** | 4 February 2014 | |

## 1 Introduction

ADHD is a neuropsychological / developmental condition with secondary behavioural, social and educational difficulties. ADHD is defined by the 'core' symptoms of inattention, hyperactivity and impulsiveness. To make a diagnosis, the core symptoms should be pervasive, present before age 7 years, and not better accounted for by other psychiatric or developmental disorders.
Diagnosis of ADHD should be based on comprehensive assessment conducted by child / adolescent psychiatrist (or nominated specialist nurse/ advanced practitioner in supervision with psychiatrist), or by a Paediatrician with expertise in ADHD.

Methylphenidate and dexamfetamine are recommended within their licensed indications, as options for the treatment of ADHD in children and adolescents. The choice between methylphenidate/ dexamfetamine, or atomoxetine (a non stimulant alternative – see separate protocol) will be based on: presence of co-morbid conditions, different adverse effects of the drugs, compliance,

potential for drug diversion with stimulants, and preference of child and carer (NICE Clinical Guideline 72 September 2008).

## 2 Scope

Pennine Care NHS Foundation Trust, associated PCTs. Acute Trust SLA partners.

## 3 Treatment of Clinical Condition using Methylphenidate or Dexamfetamine

### Licensed Indications

Methylphenidate and dexamfetamine are licensed for use as part of a comprehensive treatment programme under specialist supervision for severe ADHD, when psychological/ behavioural measures alone prove insufficient. Diagnosis should be made according to DSM-IV criteria or the guidelines in ICD-10.

Methylphenidate - is a recommended option for 1st line treatment and is licensed for children from 6 years old.

Dexamfetamine - is recommended as a 3rd line treatment for children who have tolerated, but not responded to methylphenidate, or failed to respond to atomoxetine. Dexamfetamine is licensed for children from age 3 years, but rarely used under 6 years old.

Treatment with methylphenidate/ dexamfetamine can be initiated and supervised by specialists and by GPs under advice from specialists. Continued prescribing and monitoring can be performed by GPs under shared care agreement.

### Monitoring needed:

- Pulse and blood pressure should be measured and recorded on a chart at every dose adjustment and then at least every 6 months.
- Height, weight and appetite should be recorded at least every 6 months on a growth chart.
- Patients requiring long term therapy should be carefully monitored.
- (Manufacturers recommend periodic full/ differential blood and platelet counts. However evidence indicates that chance of positive findings is very remote and outweighed by unpleasantness for the child.)

## 4 Product Information and treatment regimen to be used

Methylphenidate and dexamfetamine are classified as CNS stimulants and Schedule 2 Controlled Drugs by the British National Formulary (BNF). (Licensed indications listed above).

Administration is oral, supervised by parent/ carer, and by key staff at school for repeat dose of immediate release preparations.
Administration is usually continuous. However where ADHD symptoms are well tolerated and managed at home, families may elect to use medication term times/ school days only.

## METHYLPHENIDATE

### a) Immediate Release Preparations

| Name | Dosage<br>4 – 6 years | Dosage<br>6 – 18 years |
|---|---|---|
| Methylphenidate (generic), 5mg, 10mg & 20mg | 2.5mg twice daily increased at weekly intervals of 2.5mg<br><br>Maximum 1.4mg /kg daily in 2-3 divided doses. | 5mg once or twice daily.<br>Increased at weekly intervals by 5-10mg.<br><br>Maximum 60mg daily in 2-3 divided doses. |
| Ritalin 10mg | | |
| Equasym, 5mg, 10mg & 20mg | | |
| Medikinet, 5mg, 10mg & 20mg | | |

### b) Modified/ Extended Release Preparations

| Name | Dosage |
|---|---|
| Concerta XL<br><br>Up to 12 hours action duration (manufacturers' advice) | Once daily dose in morning<br><br>18mg, 36mg, maximum 54mg |
| Equasym XL, 10mg, 20mg & 30mg<br><br>Up to 8 hours action duration (manufacturers' advice) | Once daily dose in morning<br><br>10mg up to maximum 60mg daily |
| Medikinet XL, 10mg, 20mg, 30mg & 40mg<br><br>Up to 8 hours action duration (manufacturers' advice) | Once daily dose in morning<br><br>10mg up to maximum 60mg daily |

**DEXAMFETAMINE SULPHATE**

| Name | Dosage<br>3 – 5 years | Dosage<br>6 – 18 years |
|---|---|---|
| Dexedrine 5mg | Initially 2.5 mg once daily increased at weekly intervals by 2.5mg.<br>Maintenance dose given in 2-4 divided doses.<br><br>Maximum 1mg/kg daily up to 20mg daily. | Initially 5 – 10mg once daily increased at weekly intervals by 5mg.<br>Maintenance dose given in 2-4 divided doses.<br><br>Maximum 1mg/kg daily up to 40mg daily. |

## Product Selection

- Effectiveness and side effect profile is similar, between immediate-release and modified-release formulations of methylphenidate. Factors favouring use of single dose modified-release preparations would be issues around fluctuating control or compliance, perceived stigma of daytime doses, individual tolerance, and patient/ carer preference.

## 5 Regimen Management

a) Aspects of care for which the Consultant/ Specialist Team is responsible. 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, diagnosis of ADHD, evaluation of prior treatment, and rationalisation of treatment with methylphenidate or dexamfetamine.

- A complete history should be taken, documenting: concomitant medicines; past and present medical and psychiatric disorders/symptoms; family history of sudden cardiac death, unexplained death, or malignant arrhythmia. Complete ADHD Pre-medication Assessment Pro-forma (Appendix 1)

- Before prescribing, baseline blood pressure and pulse, height and weight should be measured and plotted on appropriate charts. Complete ADHD Pre-medication Assessment Pro-forma.

- A cardiovascular examination is required if a patient presents with cardiovascular symptoms or has a significant family history

of cardiac illness. An ECG is also recommended for those with a significant family history of cardiac illness or abnormal findings on cardiovascular examination. In this circumstance, specialist advice or assessment should be sought prior to commencing medication. (see ADHD Pre-medication Assessment Pro-forma).

- Informing patient/ carer of diagnosis, care plan, treatment including side effects, use of Patient Information Leaflets (PILs), user-friendly information for children/ adolescents.

- Dexamfetamine - discretionary advice to female adolescent patients regarding need to avoid pregnancy/ seek contraception.

- Ascertaining patient/ family's commitment to safe storage and handling of stimulant treatment.

- Initiation and titration of methylphenidate/ dexamfetamine to optimal dose or supplying instructions/directions to the GP for initiation and titration of methylphenidate/ dexamfetamine to a suitable dose.

- Promoting access to any appropriate supporting therapies, carer education, and appropriate school liaison.

- Minimum 6 monthly Specialist Team review appointments and as clinically indicated. Follow up all aspects of progress, plus height, weight, blood pressure and pulse. Also specialist will need to look out for signs of diversion, misuse and abuse of methylphenidate.

- Asking GPs if they are willing to participate in shared care and supplying instructions/directions to the GP for initiation and titration of methylphenidate/ dexamfetamine to a suitable dose.

- Written correspondence to GP from Specialist Team, summarising progress and recommendations for continued treatment.

- Reporting adverse events to the Medicines and Healthcare Products Regulatory Agency (MHRA) via Yellow Cards.

- Development of new or worsening of pre-existing, psychiatric symptoms should be monitored at every dose adjustment and then at least every 6 months, and at every visit.

- Consideration (and evaluation) of annual drug holiday to determine continued benefit.

- Discontinuation of treatment or transfer if appropriate.

- If a patient is to be discharged from specialist follow-up due to recurrent failure to attend appointments, the specialist team should write to the GP informing them of this plan and clarifying whether continued GP prescribing is recommended.

Patients should not be ideally continued on medication without specialist monitoring.

b) Conditions of assuming responsibility by the GP

Communication of satisfactory baseline physical checks.

Satisfactory directions/instructions for initiation, titration to optimum dosage, and response to treatment.

| | **Consultant** | **Usual GP** |
|---|---|---|
| Then 6 monthly follow up of height, weight, BP and pulse | Yes | N/A |
| If changes noted | Amend dose accordingly | Refer to Consultant |

c) Aspects of care for which the GP is responsible

- Replying to request for shared care as soon as possible.
- Continued prescribing of methylphenidate / dexamfetamine in the community under guidance of Consultant/ Specialist Team at the dose requested.
- Referring back to the Consultant/ Specialist Team for queries regarding treatment / side effects, and concerns about compliance or suspected drug misuse.
- Stopping treatment on the advice of the Consultant/ Specialist Team
- Reporting suspected Adverse Drug Reactions to the Consultant/ Specialist Team and MHRA

## 6 Summary of cautions, contra-indications, side effects and interactions

a) Contra-indications

**Specifically for methylphenidate**

- Diagnosis of severe depression, anorexia nervosa or anorexic disorders
- Psychotic symptoms

- Mania
- Schizophrenia
- Diagnosis or history of severe and episodic bipolar (affective) disorder that is not well controlled.
- Pre-existing cerebrovascular disorders
- Unless specialist advice has been obtained: in pre-existing cardiovascular disorders. Including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, Myocardial Infarction, potentially life threatening arrhythmias and dysfunction of cardiac ion channels.

**For methylphenidate and dexamfetamine**

- Known sensitivity to stimulants
- Angina, cardiac arrhythmia or moderate/ severe hypertension
- Psychosis
- Hyperthyroidism
- Alcohol dependence
- Glaucoma
- Breast-feeding – avoid **all** stimulants
- Pregnancy – avoid dexamfetamine
  (Methylphenidate – avoid unless potential benefits outweigh risk)

b) Cautions

- Marked anxiety or low mood
- History of self-harm or suicidal ideation.
- Methylphenidate could cause or worsen some psychiatric disorders such as depression, suicidal thoughts, hostility, anxiety, agitation, psychosis, and mania.
- Mild hypertension. Caution should be used when treating patients with methylphenidate where the underlying medical condition might be compromised by increased blood pressure or heart rate.
- Patients who develop symptoms such as palpitations exertional chest pain, unexplained syncope, dyspnoea, or other symptoms suggestive of heart disease during methylphenidate treatment should undergo prompt specialist cardiac evaluation.
- History of epilepsy
- Tics and Tourette's syndrome (for methylphenidate and dexamfetamine)
- Monitor growth in children
- Susceptibility to angle-closure glaucoma
- Previous drug misuse by young person/ carer, and continued high risk.
- Porphyria

- In psychotic children it may exacerbate behavioural disturbance and thought disorder
- Avoid abrupt withdrawal

c) Side effects

**COMMON**

- Insomnia
- Poor appetite (monitor growth in children, advise medication to be ingested after meals if problematic)
- Headache
- Labile mood/ irritability
- Nausea, vomiting, stomach ache

**LESS COMMON**

- Tics
- Visual disturbance/hallucinations
- Increased heart rate or BP, dry mouth
- Itching or nose bleed
- Isolated cases of leucopenia, thrombocytopenia, anaemia (FBC indicated if marrow suppression suspected)
- Angle-closure glaucoma

d) Interactions

MAOI's, SSRI's, tricyclic antidepressants, phenytoin, primidone, barbiturates, volatile liquid general anaesthesia

Please also check the latest list of interactions contained within the current edition of the British National Formulary (BNF) and BNF for Children.

## 7 Special considerations

Handover for shared care largely by written agreement. Individual consideration of patients to occur when issues of tolerance, inconsistent response to treatment, pre-existing medical conditions or issues of patient compliance.

Misuse potential of stimulants to be minimised by careful selection of patients for treatment, smaller quantities given at repeat prescription, prompt discussion between GP and specialist service with review or termination of treatment in event of non-attendance or suspected drug misuse.

## 8 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.

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

## 9 Statement of agreement

This form is a request by the consultant to share the suggested care pathway of your patient. Shared care is an agreement between the GP and the Consultant. If you are unable to agree to the sharing of care and initiating the suggested medication, please make this known to the consultant within 14 days, ideally stating the nature of your concern.

## 10 Written information provided to the patient

- Pennine Care NHS Foundation Trust Patient Information Leaflet
- NICE Technology Appraisal 98: Information for the public

## 11 Supporting References


- NICE Clinical Guideline 72. Attention deficit hyperactivity disorder. September 2008 www.nice.org.uk/CG072
- NICE Technology Appraisal 98: Methylphenidate, atomoxetine and dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and adolescents March 2006. www.nice.org.uk/TA098
- BNF Number 60, September 2010.
- BNF for Children, 2010-2011.
- Summary of Product Characteristics. www.medicines.org.uk. Accessed January 2010.
- MHRA. Drug Safety Update. Volume 2. Issue 8**.** www.mhra.gov.uk. Accessed January 2010.

**ADHD PRE-MEDICATION ASSESSMENT PRO FORMA Appendix 1**

**Name of Child: _____ Date:_____**

**DOB: _____ RT NO: _____**

**Consultant/Psychiatrist: _____Case Worker:_____**

Please clarify if previous or current history

| | **Child** | **Family** |
|---|---|---|
| Significant anxiety | | |
| Expresses suicidal ideas | | |
| Low mood or depression | | |
| Angina/MI under 55 or history of sudden death | | |
| High or low BP/P | | |
| Arrhythmia | | |
| History of exercise syncopy or cardiovascular Symptoms | | |
| Epilepsy | | |
| Drug/alcohol misuse or dependency | | |
| Tics/Tourettes | | |
| Thyroid Disorder | | |
| Glaucoma | | |
| Kidney Disease | | |
| Liver Disease | | |

**Drug allergies:**

**Other medication prescribed:**

**Clinical examination:**

**Height:_____ Centile _____**

**Weight:_____ Centile _____**

**Plot on centile charts**

**B/P: _____Pulse _____**

**<u>Cardiovascular examination</u>**

If family history of sudden death, MI under 55 or young person with history of cardiovascular symptoms e.g. exercise syncope or breathlessness.

**Options:**

1. CAMHS, including documentation of findings.
2. PAEDS. Referral
3. GP. Referral

ECG if abnormal physical examination or significant family history of cardiovascular illness. Seek paediatric advice or assessment prior to commencing treatment.