
	<p><b>PAN MERSEY AREA PRESCRIBING COMMITTEE</b>  <b>SHARED CARE FRAMEWORK</b>  <b>REF: SC15 FINAL</b>  <b>APC BOARD DATE: 30 NOV 2016</b></p>	 <b>Pan Mersey</b> Area Prescribing Committee
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## METHYLPHENIDATE

<p><b>1. Background</b></p>	<p><b><u>Attention deficit hyperactivity disorder (ADHD):</u></b>          ADHD is a chronic, neurodevelopmental disorder associated with inattention, hyperactivity and impulsiveness.</p> <p>The National Institute for Health and Clinical Excellence (NICE) issued a clinical guideline, Attention Deficit Hyperactivity Disorder: diagnosis and management (NG87) in 2018. This document advises that treatment for ADHD should only be initiated by a healthcare professional with expertise in ADHD and should be based on a comprehensive assessment and diagnosis. Continued prescribing and monitoring of drug therapy may be performed by the primary care clinicians, under shared care arrangements.</p> <p>Methylphenidate, atomoxetine, dexamfetamine, lisdexamfetamine and guanfacine are recommended within their licensed indications, as options for the management of ADHD. Some prescribing of ADHD medication is 'off-label' but clearly supported by the NICE guideline, British National Formulary (BNF) and BNF for Children.</p> <p>Symptoms of ADHD can persist into adulthood in about two thirds of all patients. For patients transitioning into adulthood, specialists should ensure appropriate arrangements are made for referral into adult services. In such circumstances a new shared care agreement will need to be made between the primary care clinician and the new secondary care provider.</p> <p><b><u>Narcolepsy:</u></b>          Narcolepsy is a rare, long-term sleep disorder which affects the brain's ability to regulate the normal sleep-wake cycle. This can lead to symptoms such as excessive daytime sleepiness including the sudden urge to sleep, and disturbed night-time sleep. In addition, some patients may experience sudden episodes of a related condition, cataplexy, potentially causing dangerous falls and increasing the risks of accidents, including car accidents</p> <p>Modafinil is the first-line pharmacological treatment for excessive daytime sleepiness and irresistible episodes of sleep. When excessive daytime somnolence coexists with cataplexy and poor sleep, sodium oxybate may be prescribed. Dexamfetamine and methylphenidate (unlicensed indication) may be options where modafinil is insufficiently effective and sodium oxybate is not recommended. Moreover, the short-acting effect of methylphenidate may be useful when modafinil needs to be supplemented at a specific time of the day, or in situations where maximum alertness is required.</p> <p>[EFNS guidelines on management of narcolepsy. European Journal of Neurology 2006,13:1035-1048]</p>
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<b>2. Mode of Action</b>	Methylphenidate is a mild central nervous system (CNS) stimulant. The mode of action of amfetamines in ADHD is not fully established. Methylphenidate is thought to work by blocking the reuptake of dopamine and noradrenaline into the presynaptic neurone and releasing dopamine and noradrenaline into the extraneuronal space.	
<b>3. Licensed Indications</b>	Methylphenidate is indicated as part of a comprehensive treatment programme for attention deficit hyperactivity disorder in children and adolescents aged 6 years and over when remedial measures alone prove insufficient. Treatment must be under the supervision of a specialist in behavioural disorders.	
<b>4. Locally agreed off label indications</b>	<p>This document supports the following off label uses (denoted by *):</p> <p><u>Attention Deficit Hyperactivity Disorder (ADHD)</u></p> <ul style="list-style-type: none"> <li>• Continuation of treatment into adulthood for adolescents whose symptoms persist into adulthood and who have shown clear benefit from treatment</li> <li>• Treatment of ADHD in adults aged 18 years and over</li> <li>• Treatment of ADHD in children under 6 years (exceptional use)</li> <li>• Doses higher than licensed by the manufacturer, up to a maximum of 90mg (children) and 100mg (adults), or equivalent for MR preparations, see BNF/BNFc.</li> </ul> <p><u>Narcolepsy</u></p> <ul style="list-style-type: none"> <li>• Treatment of excessive sleepiness in narcolepsy</li> </ul>	
<b>5. Contraindications</b>	<p><i>(Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Refer to the manufacturers SPC for complete up-to-date list.)</i></p> <ul style="list-style-type: none"> <li>• Known sensitivity to methylphenidate or intolerance to any of the excipients</li> <li>• Glaucoma</li> <li>• Phaeochromocytoma</li> <li>• Treatment with MAO inhibitors, or within a minimum of 14 days of discontinuing those drugs.</li> <li>• Hyperthyroidism or thyrotoxicosis</li> <li>• Severe psychiatric comorbidities that are not well-controlled</li> <li>• Pre-existing cerebrovascular or cardiovascular disorders</li> </ul> <p><u>Link to SPC</u></p>	
<b>6. Pharmaceutical aspects</b> <i>(including route of administration, formulation, method of administration, legal category)</i>	Route of Administration	Oral
	Formulation	<p>Various preparations of methylphenidate are available:</p> <ul style="list-style-type: none"> <li>• Immediate release tablets, 5mg, 10mg and 20mg tablets.</li> <li>• Prolonged release capsules - 10mg, 20mg, 30mg, 40mg, 50mg and 60mg</li> <li>• Prolonged release tablets 18mg, 27mg, 36mg and 54mg</li> </ul> <p>The choice of formulation of methylphenidate will be decided by the specialist on an individual basis, depending on the individual needs of the patient.</p>

	<p>Method of administration</p>	<ul style="list-style-type: none"> <li>• Immediate release (IR) tablets should be swallowed with a drink of water, either with meals or after meals. IR tablets can be split along the break line for ease of swallowing.</li> <li>• Modified release preparations should be swallowed whole with sufficient liquid, with or without food and must not be chewed, divided or crushed.</li> <li>• Contents of modified release capsules may be sprinkled on a tablespoon of apple sauce or yogurt then swallowed immediately without chewing. Drinking some fluids, e.g. water, should follow the intake of the sprinkles.</li> </ul>
	<p>Other important information</p>	<ul style="list-style-type: none"> <li>• Different modified-release preparations may not have the same clinical effect. To avoid confusion between different formulations of methylphenidate, prescribers should specify the brand to be dispensed.</li> <li>• Methylphenidate should be withdrawn slowly to avoid inducing depression or renewed hyperactivity</li> <li>• Modified release tablets not appropriate for use in dysphagia or if gastro-intestinal lumen restricted.</li> <li>• For some modified release tablet formulations, the membrane may pass through gastro-intestinal tract unchanged.</li> <li>• Alcohol may exacerbate the CNS adverse effects of methylphenidate. It is advisable for patients to abstain from alcohol during treatment.</li> <li>• Caution should be exercised when prescribing methylphenidate to those likely to be at risk of stimulant misuse or diversion</li> </ul>
	<p>Legal Category</p>	<p>Methylphenidate is a Schedule 2 Controlled Drug and prescriptions must comply with full legal requirements for the prescribing and supply of controlled drugs.</p> <p>NICE NG46 recommends prescribing enough of a controlled drug to meet the person's clinical needs for no more than 30 days, unless there are exceptional circumstances.</p>
<p><b>7. Specialist initiation and titration</b></p>	<p><b><u>Attention Deficit Hyperactivity Disorder:</u></b></p> <p><u>Immediate-release preparations:</u></p> <ul style="list-style-type: none"> <li>• Children 6–18 years, initially 5 mg 1–2 times daily, increased if necessary at weekly intervals by 5–10 mg daily; usual max. 60 mg daily in 2–3 divided doses; may be increased to 2.1 mg/kg daily in 2–3 divided doses (up to a maximum of 90 mg* daily).</li> <li>• *Adults over 18 years [unlicensed use], 5 mg 2–3 times daily increased if necessary at weekly intervals according to response, (up to a maximum of 100 mg* daily in 2–3 divided doses)</li> </ul> <p><u>Modified-release preparations:</u></p> <ul style="list-style-type: none"> <li>• Doses of modified-release preparations may vary according to the brand chosen. Initial doses as per manufacturer SPC or BNF given once daily and no more than twice daily.</li> <li>• Patients established on an immediate-release methylphenidate hydrochloride formulation may be switched to the equivalent daily dose of a modified-release formulation</li> </ul> <p>In order to optimise drug treatment, the initial dose should be titrated against symptoms and side effects over 4–6 weeks. Doses should be gradually</p>	

	<p>increased until there is no further clinical improvement in ADHD (that is, symptom reduction, behaviour change, improvements in education and/or relationships) and side effects are tolerable.</p> <p>Treatment should be discontinued if there is no response after 1 month of maximum tolerated dose.</p> <p><b><u>Narcolepsy*</u></b> 10–60 mg daily in divided doses; usual dose 20–30 mg daily in divided doses, dose to be taken before meals. (BNF)</p> <p>M/R preparations - Usually 18-54mg daily but the effective dose may be increased in exceptional circumstances to up to a maximum of 108mgdaily.</p> <p><b>Shared Care may only be commenced following specialist initiation, stabilisation and review of treatment. In addition, formal agreement must have been received from the primary care prescriber.</b></p>	
<p><b>8. Dosage regimen for continued prescribing in Primary Care</b></p>	<p><b><i>Following initiation and stabilisation continue prescribing and monitoring as advised by the specialist in accordance with the shared care agreement.</i></b></p>	
	<p><b>Duration of treatment</b> <i>To be determined by the specialist based on clinical response and tolerability.</i></p>	<p><b><u>ADHD</u></b> Following an adequate treatment response, methylphenidate should be continued for as long as it remains clinically effective. This should be reviewed by the specialist at least annually [NICE CG72]</p> <p>Trial periods off medication (drug holiday) to assess the patient's condition without treatment may be deemed appropriate by the ADHD specialist; this will be undertaken and supervised by the specialist who will advise the patient and GP of the outcome</p> <p><b><u>Narcolepsy</u></b> The duration of treatment will be determined by the specialist team.</p>
	<p><b>Termination of treatment</b></p>	<p>This will be carried out by the specialist</p>
	<p><b>NB. All dose adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the GP.</b></p>	
<p><b>9. Significant Drug Interactions</b></p> <p><i>For a comprehensive list consult the BNF or Summary of Product Characteristics</i></p>	<p><b>Seek advice from the initiating specialist if any of the following drugs are co-prescribed.</b></p> <p><b>Coumarin anticoagulants</b> (e.g. warfarin): Possibly reduces metabolism and enhances anticoagulant effect. Dose adjustment of warfarin may be needed.</p> <p><b>Antiepileptic drugs:</b> Carbamazepine may decrease levels of methylphenidate; monitor response. Methylphenidate dose adjustments may be necessary. Levels of phenytoin and phenobarbitone may be increased by methylphenidate leading to toxicity.</p> <p><b>Antidepressants</b> (tricyclic and selective serotonin reuptake inhibitors). Increased risk of adverse effects and serotonin syndrome.</p> <p><b>MAOIs:</b> Contraindicated; risk of hypertensive crisis.</p> <p><b>Antihypertensive medication.</b> Possible decrease in antihypertensive effectiveness.</p> <p><b>Clonidine:</b> Safety of using in combination with methylphenidate not evaluated.</p>	

	<p><b>Medication that elevates blood pressure</b> (e.g. sympathomimetics), Increased risk of hypertension</p> <p><b>Antipsychotics.</b> Possible decreased effectiveness and increased risk of side effects of antipsychotics.</p> <p><b>HIV-protease inhibitors</b> concurrent use with amfetamines increases the concentration of amfetamines and is potentially fatal. Avoidance or dose reduction is advised.</p> <p>The urinary excretion of amfetamines is increased by <b>urinary acidifiers</b> and reduced by <b>urinary alkalinisers.</b></p> <p><b>Halogen anaesthetics:</b> Risk of sudden blood pressure increase during surgery</p>
<p><b>10. Adverse drug reactions</b></p> <p><i>For a comprehensive list consult the BNF or Summary of Product Characteristics</i></p>	<p>The most common adverse effects include:</p> <ul style="list-style-type: none"> <li>• Metabolic effects such as decreased appetite with moderately reduced weight and growth during prolonged use.</li> <li>• Psychiatric effects such as aggression, agitation, labile affect, irritability mood swings, and depression.</li> <li>• Central nervous system effects such as insomnia, nervousness, headache, drowsiness, dizziness, tremor, tics, confusion, and psychomotor hyperactivity</li> <li>• Cardiovascular system effects such as hypertension, tachycardia, palpitations, chest pain and arrhythmias.</li> <li>• Gastrointestinal effects such as diarrhoea, abdominal cramps, nausea, vomiting, dyspepsia, dry mouth and anorexia.</li> <li>• Dermatological effects such as pruritus, rash</li> <li>• Urogenital effects such as sexual dysfunction.</li> <li>• Renal and urinary effects such as renal impairment, urinary frequency.</li> <li>• Ophthalmological effects such as mydriasis, blurred vision.</li> </ul> <p><u>In children</u>, parents/patients will have been advised by the ADHD specialist to report any suspected side effects directly to them. GPs should refer any patients with suspected side effects to the ADHD specialist irrespective of the advice in the following table.</p>

<b>Adverse drug reactions</b> - continued	<b>Adverse event</b> <small>System – symptom/sign</small>	<b>Action to be taken and by whom</b>
	Sustained resting tachycardia, exertional chest pain, dyspnoea and unexplained syncope or other symptoms suggestive of cardiac disease.	Discontinue treatment. Seek prompt cardiac specialist advice and notify the initiating specialist team
	Clinically significant increases in blood pressure, arrhythmia	Exclude other causes and seek advice from the initiating specialist. Dose reduction may be appropriate.
	Reduced weight and growth retardation	Continue treatment. Provide advice on healthy diet. The patient should be advised to consider taking additional meals or snacks early in the morning or late in the evening when the effects of the drug have worn off. Refer to a dietician if appropriate. If weight loss becomes a concern, seek ADHD specialist advice.
	Increase in seizure frequency or new-onset seizures	Refer to the initiating specialist team. Discontinuation or switching of treatment may be appropriate.

	Development or worsening of psychiatric disorders including psychotic or manic symptoms, aggressive or hostile behaviour, anxiety, agitation, motor or vocal tics and suicidal ideation	Refer to the initiating specialist team. Depending on symptoms, discontinuation of treatment, dose reduction or switching may be considered by the ADHD specialist
	Central nervous system effects such as dizziness, dyskinesia, psychomotor hyperactivity, headache	Usually temporary. If persisting, refer to initiating specialist. Dose reduction or discontinuation of treatment may be appropriate.
	Severe blood, kidney and liver disorders	Exclude other causes. Repeat blood tests for confirmation. Seek initiating specialist advice if the adverse effect is secondary to the drug. Discontinuation of treatment may be considered.
	Glaucoma or other severe visual disturbances	Seek ophthalmological advice and notify the initiating specialist Team. Discontinuation of treatment may be considered by the ADHD specialist
	Diarrhoea, abdominal cramps, nausea, vomiting <i>(usually occur at the beginning of treatment)</i>	Continue treatment. Initial symptoms may be alleviated by concomitant food intake. Exclude other causes. Seek initiating specialist advice if symptoms become severe. Dose reduction or discontinuation of treatment may be considered
	Insomnia	Continue treatment, usually transient. Provide sleep hygiene advice. Dose and timing of dose may need to be adjusted with initiating specialist advice.
	<b>WARNING:</b> Methylphenidate can cause dizziness, drowsiness and visual disturbances. It can impair cognitive function and affect the patient's ability to drive safely. This class of medicine is in the list of drugs included in regulation under 5a of the Road Traffic Act 1988.	
	Any serious reaction to methylphenidate should be reported to the MHRA via the "Yellow Card" scheme <a href="http://yellowcard.mhra.gov.uk/">http://yellowcard.mhra.gov.uk/</a>	
<b>11. Advice to patient/carers</b>	The patient should be advised to report any of the following signs or symptoms to their GP without delay:  Symptoms suggestive of cardiac or psychiatric disorders or seizures. It is advisable for patients to abstain from alcohol during treatment. Alcohol can worsen the side effects of methylphenidate.  In children, parents/patients will have been advised by the ADHD specialist to report the above signs or symptoms directly to them.	
<b>12. Pregnancy and breast feeding</b>	Seek specialist advice for prescribing decision.	
<b>13. Baseline investigations to be undertaken by the specialist centre</b>	<ul style="list-style-type: none"> <li>• A comprehensive history of concomitant medications</li> <li>• Full mental health and social assessment</li> <li>• Full medical history and physical examination including <ul style="list-style-type: none"> <li>- Assessment of history of exercise syncope, undue breathlessness and other cardiovascular symptoms</li> <li>- Heart rate and blood pressure</li> <li>- Weight (in adults); height and weight plotted on a growth chart (in children and adolescents); repeat following each dose adjustment and at 3 months and 6 months after treatment has started</li> <li>- Family history of cardiac disease and examination of the cardiovascular system.</li> </ul> </li> </ul>	

	<ul style="list-style-type: none"> <li>- Pregnancy or breastfeeding</li> <li>• An ECG 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 cardiac examination.</li> <li>• Risk assessment for substance misuse and drug diversion (where the drug is passed on to others for non-prescription use).</li> </ul>	
<b>14. Ongoing monitoring requirements to be undertaken by the specialist team and Primary Care</b>	<b>Monitoring</b>	<b>Frequency</b>
	Blood pressure and pulse (appropriate for age, using information supplied in attached request letter – children & adolescents only)	At every adjustment of dose or visit and then every 6 months Primary Care every 6 months
	Weight (in adults); Height and weight (in children and adolescents)	At every adjustment of dose or visit and then every 6 months Primary Care every 6 months  Weight every 3 months in children 10 years and under
	Compliance Indication of abuse, misuse or diversion of methylphenidate	Every 6 months
	Side effects	Every 6 months
	Clinical need, benefits, side effects	Annual review by Specialist
	Refer to 'Adverse Drug Reactions' section for advice and actions to be taken.	
<b>15. Specialist contact information</b>	<b>If stopping medication or needing advice</b> , please refer to the shared care agreement (Appendix 2)	
<b>16. Additional information</b>	<b>Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.</b>	
<b>17. References</b>	<ol style="list-style-type: none"> <li>1. Various summaries of product characteristics for methylphenidate</li> <li>2. NICE guidelines (NG87) February 2018: Attention deficit hyperactivity disorder: diagnosis and management</li> <li>3. NICE CKS for ADHD</li> <li>4. British National Formulary</li> <li>5. British National Formulary for Children</li> </ol>	
<b>18. To be read in conjunction with the following documents</b>	Shared Care Policy (appendix 1) Shared Care Agreement (appendix 2)	

## **Appendix 1 Policy for Shared Care**

Shared care is only appropriate if it provides an optimum solution for the patient and it meets the criteria outlined in the Shared Care section of the Pan Mersey **Definitions and Criteria for Categorisation of Medicines in the Pan Mersey Formulary** document.

Before prescribing responsibilities are transferred to primary care:

- Prescribing responsibility will only be transferred when the consultant and the patient's GP agree that the patient's condition is stable.
- All information required by the shared care framework for the individual medicine has been provided to the patient's GP.
- Patients will only be referred to the GP once the GP has agreed to the Shared Care Agreement and returned signed copies.

**Inherent in any shared care agreement is the understanding that participation is at the discretion of the GP, subject to the availability of sufficient information to support clinical confidence.**

### **Specialist Responsibilities in Shared Care**

- To initiate the medicine, prescribing and monitoring toxicity and efficacy as required until the patient is stabilised and reviewed as described by the shared care framework.
- To ensure the patient or their carer is counselled with regard to the medicine.
- To provide any necessary written information to the patient with regard to the individual medicine.
- To be familiar with the shared care framework.
- To provide all information to the patient's GP as required by the shared care framework when prescribing responsibility is initially transferred and at any subsequent times as necessary for safe and effective treatment of the patient.
- To assess the patient regularly as necessary for the duration of therapy as specified in the individual medicine shared care framework.
- To review the patient promptly if required by the GP concerned.
- To meet any additional requirements as required by the individual medicine shared care framework.
- To communicate failure of a patient to attend a routine hospital review and advise the GP of appropriate action to be taken.



- Following the addition of a new drug to an existing regime covered by a Shared Care Agreement, the Specialist must recall the patient for re-titration, stabilisation and subsequent review and inform the GP of this. A new Shared Care Agreement must then be initiated.

### **Primary Care Responsibilities in Shared Care**

- To reply to a written request for Shared Care within 21 days ensuring both copies of the Shared Care Agreement are signed if appropriate.

If agreeing to shared care, the GP is asked to:

- To provide prescribe or manage and monitor the medicine as advised by the Specialist and in line with the individual Shared Care Framework.
- To review the patient as required by the Shared Care Framework
- To make appropriate and contemporaneous records of prescribing and/or monitoring and to note the existence of the Shared Care Agreement on the patient`s clinical record. A READ code of “6652 Shared Care- Specialist/GP” can be used.
- To be familiar with the individual Shared Care Framework.
- To monitor patient`s general wellbeing.
- To report any adverse effects of treatment to the consultant
- To inform the Specialist of any relevant change in the patient`s circumstances.
- To seek Specialist advice as appropriate.
- To meet any additional requirements as required by the individual Shared Care Framework.
- To respond to Specialist communication relating to any change or addition to the patients treatment covered by the Shared Care Agreement.

**Appendix 2:                    Shared Care Agreement**

**Request by Specialist Clinician for the patient’s GP to enter into a shared care agreement**

**Part 1**

**To be signed by Consultant / Prescribing Member of Specialist Team**

Date \_\_\_\_\_

Name of patient \_\_\_\_\_

Address \_\_\_\_\_  
\_\_\_\_\_

Patient NHS No \_\_\_\_\_

Patient hospital unit No \_\_\_\_\_

Diagnosed condition \_\_\_\_\_

If using addressograph label please attach one to each copy

Dear Dr \_\_\_\_\_

I request that you prescribe

(1) \_\_\_\_\_

(2) \_\_\_\_\_

for the above patient in accordance with the enclosed shared care framework.

**Last Prescription Issued: ..... / ..... / ..... Next Supply Due: ..... / ..... / .....**

**I confirm that the patient has been stabilised and reviewed on the above regime in accordance with the Shared Care Framework and Policy.**

**I confirm that if this is a Shared Care Agreement for a drug indication which is unlicensed or off label, informed consent has been received.**

## Details of Specialist Clinicians

Name \_\_\_\_\_ Date \_\_\_\_\_

*Consultant / Prescribing Member of Specialist Team \*circle or delete as appropriate*

Signature \_\_\_\_\_

In all cases, please also provide the name and contact details of the Consultant.

When the request for shared care is made by a prescriber who is not the consultant, it is the supervising consultant who takes medico-legal responsibility for the agreement.

**Consultant:** \_\_\_\_\_

### Contact details:

Telephone number: \_\_\_\_\_ Ext: \_\_\_\_\_

Address for return  
of documentation \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

## Part 2

### To be completed by Primary Care Clinician

I agree to prescribe \_\_\_\_\_ for the above

patient in accordance with the enclosed shared care framework.

GP signature \_\_\_\_\_ Date \_\_\_\_\_

GP name \_\_\_\_\_ Please print

**GP:** *Please sign and return a copy **within 21 calendar days** to the address above*

## OR

**GP-** If you do not agree to prescribe, please delete the section above and provide any supporting information as appropriate below: