This policy statement is approved by Southport and Formby, South Sefton, CCGs

Southport and Formby | South Sefton

NHS

South Sefton Clinical Commissioning Group
Southport and Formby Clinical Commissioning Group

Shared Care Framework for

Methylphenidate for the treatment of ADHD in adults

Date approved by Joint Medicines Operational Group 5/10/2018

1. Background	Attention deficit hyperactivity disorder (ADHD) is a chronic, neurodevelopmental disorder associated with inattention, hyperactivity and impulsiveness. In about two thirds of all patients' symptoms of ADHD can persist into adulthood. NICE recommend that treatment for ADHD should 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 can be performed by the primary care clinicians, under shared care arrangements.
2. Licensed Indications	ADHD in children over 6 years and adolescents
3. Locally agreed off- label indications	ADHD in adults including: • Continuation of treatment into adulthood for adolescents whose symptoms persist into adulthood and who have shown clear benefit from treatment • Treatment of ADHD in adults aged 18 years and over • Doses higher than licensed by the manufacturer, up to a maximum of 100mg, or equivalent for MR preparations.
4. Specialist Initiation and dose titration	<u>ADHD:</u> Immediate Release preparations: • 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 - Modified-release preparations: • Doses of modified-release preparations will vary according to the brand chosen. Initial doses as per manufacturer SPC or BNF given once daily and no more than twice daily • The initial dose should be titrated against symptoms and side effects over 4–6 weeks • Treatment should be discontinued if there is no response after 1 month of maximum tolerated dose. • All dose adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician. **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**.

<table>
<tr>
<td>5. Baseline investigations, initial monitoring and dose titration to be undertaken by the specialist.</td>
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Baseline Investigations:
• A comprehensive history of concomitant medications
• Full mental health and social assessment
• Full medical history and physical examination including:
- assessment of history of exercise, syncope, undue breathlessness and other cardiovascular symptoms
- Heart rate and blood pressure plotted on a centile chart
- Weight
- Family history of cardiac disease
- Examination of t h e cardiovascular system.
- Pregnancy or breastfeeding status
• 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.
• Risk assessment for substance misuse and drug diversion.

Ongoing monitoring by specialist:
• To optimise drug treatment, the initial dose should be titrated against symptoms and side effects over 4–6 weeks. Doses are gradually increased until there is no further clinical improvement in ADHD symptoms (behaviour change, improvements in education and or relationships) and side effects are tolerable
• Blood pressure and pulse every 6 months or at each visit and after every dose adjustment.
• Clinical need, benefit and side effects should be reviewed annually
• Weight 3 months after starting treatment then every 6 months and at each visit or after every dose adjustment.
• Treatment should be discontinued if there is no response after 1 month of maximum tolerated dose.

Duration of treatment to be determined by the specialist based on clinical response and tolerability.

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

Termination of treatment will be carried out by the specialist
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<td rowspan="5">6. Ongoing monitoring requirements to be undertaken by Primary Care.</td>
<td colspan="2">Following initiation and stabilisation continue prescribing and monitoring as advised by the specialist in accordance with the shared care agreement.</td>
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<tr>
<td>Blood pressure and pulse</td>
<td>Every 6 months</td>
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<tr>
<td>Weight</td>
<td rowspan="3">Every 6 months</td>
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<tr>
<td>Compliance check including checking for any signs of diversion</td>
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<td>Side effects</td>
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7. Pharmaceutical aspects *(including route of administration, formulation, method of administration, legal category)*	Route of administration	Oral
	Formulation	Various preparations of methylphenidate are available: - Immediate release tablets, 5mg, 10mg and 20mg tablets. - Prolonged release capsules - 10mg, 20mg, 30mg, 40mg, 50mg and 60mg - Prolonged release tablets 18mg, 27mg, 36mg and 54mg The choice of formulation of methylphenidate will be decided by the specialist on an individual basis, depending on the individual needs of the patient. This should be in line with the commissioner's recommendation
	Method of Administration	- 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. - Modified release preparations should be swallowed whole with sufficient liquid, with or without food and must not be chewed, divided or crushed. - Contents of modified release capsules may be sprinkled on a tablespoon of apple sauce or yogurt then swallow immediately without chewing. Drinking some fluids, e.g. water, should follow the intake of the sprinkles.
	Other important information	- 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. - Methylphenidate should be withdrawn slowly to avoid inducing depression or renewed hyperactivity - Modified release tablets not appropriate for use in dysphagia or if gastro- intestinal lumen restricted. - For some modified release tablet formulations, the membrane may pass through gastro-intestinal tract unchanged. - Alcohol may exacerbate the CNS adverse effects of methylphenidate. It is advisable for patients to abstain from alcohol during treatment.

		• Caution should be exercised when prescribing methylphenidate to those likely to be at risk of stimulant misuse or diversion
	Legal category	Methylphenidate is a **Schedule 2 Controlled Drug** and prescriptions must comply with full legal requirements for the prescribing and supply of controlled drugs. 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.
8. Contraindications *(Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.)*	• Known sensitivity to methylphenidate or intolerance to any of the excipients • Glaucoma • Phaechromocytoma • Treatment with MAO inhibitors, or within a minimum of 14 days of discontinuing those drugs. • Hyperthyroidism or thyrotoxicosis • Severe psychiatric comorbidities that are not well controlled • Pre-existing cerebrovascular or cardiovascular disorders	
9. Significant Drug Interactions *(For a comprehensive list consult the BNF or Summary of Product Characteristics)*	Seek advice from the initiating specialist if any of the following drugs are co-prescribed. **Coumarin anticoagulants** (e.g. warfarin): Possibly reduces metabolism and enhances anticoagulant effect. Dose adjustment of warfarin may be needed. **Antiepileptic drugs**: 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. **Antidepressants** (tricyclic and selective serotonin reuptake inhibitors). Increased risk of adverse effects and serotonin syndrome. **MAOIs:** Contraindicated; risk of hypertensive crisis. **Antihypertensive medication**. Possible decrease in antihypertensive effectiveness. **Clonidine:** Safety of using in combination with methylphenidate not evaluated. **Medication that elevates blood pressure** (e.g. sympathomimetics), Increased risk of hypertension **Antipsychotics**. Possible decreased effectiveness and increased risk of side effects of antipsychotics. **HIV-protease inhibitors** concurrent use with amfetamines increases the concentration of amfetamines and is potentially fatal. Avoidance or dose reduction is advised.	

	The urinary excretion of amfetamines is increased by **urinary acidifiers** and reduced by **urinary alkalinisers.** **Halogen anaesthetics:** Risk of sudden blood pressure increase during surgery
10. Adverse effects and management *(For a comprehensive list consult the BNF or Summary of Product Characteristics)*	The most common adverse effects include: • Metabolic effects such as decreased appetite with moderately reduced weight and growth during prolonged use. • Psychiatric effects such as aggression, agitation, labile affect, irritability mood swings, and depression. • Central nervous system effects such as insomnia, nervousness, headache, drowsiness, dizziness, tremor, tics, confusion, and psychomotor hyperactivity • Cardiovascular system effects such as hypertension, tachycardia, palpitations, chest pain and arrhythmias. • Gastrointestinal effects such as diarrhoea, abdominal cramps, nausea, vomiting, dyspepsia, dry mouth and anorexia. • Dermatological effects such as pruritus, rash • Urogenital effects such as sexual dysfunction. • Renal and urinary effects such as renal impairment, urinary frequency. • Ophthalmological effects such as mydriasis, blurred vision.

Adverse Effect	Action
Sustained resting tachycardia, exertional chest pain, dyspnea 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.
Reduced weight	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. If weight loss becomes a concern, seek ADHD specialist advice
Increase in seizure frequency or new-onset seizures	Refer to the initiating specialist team.
Development or worsening of psychiatric disorders including psychotic or manic symptoms, aggressive or hostile behavior, anxiety, agitation, motor or vocal tics and suicidal ideation	Refer to the initiating specialist team.
Central nervous system effects such as dizziness, dyskinesia, psychomotor hyperactivity, headache	Usually temporary. If persisting, refer to initiating specialist.

	Severe blood, kidney and liver disorders (incidental finding on blood tests)	Exclude other causes. Repeat blood tests for confirmation. Seek ADHD specialist advice if it is suspected the adverse effect is secondary to the
	Glaucoma or other severe visual disturbances	Seek ophthalmological advice and notify the initiating specialist team
	Diarrhea, abdominal cramps, nausea, vomiting *(usually occur at the beginning of treatment)*	Continue treatment. Initial symptoms may be alleviated by concomitant food intake. Exclude other causes. Seek initiating specialist advice if symptoms become severe.
	Insomnia	Continue treatment, usually transient. Provide sleep hygiene advice. Contact specialist for advice as dose and timing of dose may need to be adjusted
	Any serious reaction to dexamphetamine should be reported to the MHRA via the "Yellow Card" scheme on http://yellowcard.mhra.gov.uk/	
11. Advice to patient and carers	Patients should be informed 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 The patient should be advised to report any signs or symptoms suggestive of cardiac, psychiatric disorders or seizures to their GP without delay It is advisable for patients to abstain from alcohol during treatment as alcohol can worsen the side effects of methylphenidate.	
12. Pregnant or Breast feeding	Methylphenidate is contraindicated in pregnancy refer to initiating specialist	
13. Specialist Contact Information	Mersey Care NHS Foundation Trust South Sefton Neighbourhood Centre Park Road Waterloo Liverpool L22 3XR Tel: 0151 330 8500	
14. Additional information	Where patient care is transferred from one provider to another, a new shared care agreement must be completed.	
15. References	1. Various summaries of product characteristics for Methylphenidate 2. NICE guidelines (CG72) 2008: Attention deficit hyperactivity disorder: diagnosis and management **Updated August 2018** with Nice Guidelines (NG87) 2018: Attention deficit hyperactivity disorder: diagnosis and management https://www.nice.org.uk/guidance/ng87 3. NICE CKS for ADHD 4. British National Formulary	

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, prescribe, monitor for toxicity and efficacy as described by the shared care framework until the patient is stabilised.
- To ensure the patient or their carer:
    - Is counselled with regard to the risks and benefits of the medicine.
    - Provide any necessary written information to the patient with regard to the individual medicine including patient information leaflets on individual drugs.
    - Obtain and document informed consent from the patient when any medicines is prescribed for an off-label indication for any condition
- 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.
- 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 initiate, prescribe and monitor the new drug in accordance with the relevant shared care agreement including subsequent review and inform the GP of this. A new Shared Care Agreement must then be initiated for the new drug.

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 report any adverse effects of treatment to the specialist team.
- 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 patient’s 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 / Associate Specialist / Specialist registrar or Specialist Nurse (who must be a prescriber)

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 / Associate Specialist / Specialist Registrar / Specialist Nurse ****circle or underline 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 Specialist Nurse, 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

Part 3 Other Relevant Information

Part 4 Monitoring Requirements

Monitoring requirements are detailed in section 6 of the attached shared care framework.

Date	Weight	Pulse	Blood Pressure
Refer if:	[Please specify threshold]	[Please specify threshold]	[Please specify threshold]

Details of any recent relevant monitoring results:

Previous investigations completed	**Date**	**Result**	**Next date due**