

#### SHARED CARE FRAMEWORK

# The Pan Mersey Area Prescribing Committee recommends the prescribing of METHYLPHENIDATE for ADHD in accordance with NICE NG87.

#### **SHARED CARE**

#### 1. Background

NHS Halton CCG for the treatment of adults only
NHS Knowsley CCG for the treatment of adults only
NHS St Helens CCG for the treatment of adults only
NHS Warrington CCG for the treatment of adults only
NHS Wirral CCG for the treatment of adults only

This shared care framework aims to provide clarity on the responsibilities of all professionals involved in commissioning and prescribing across primary, secondary and tertiary care. Good organisation of care across the interface between primary and secondary/tertiary care is crucial in ensuring that patients receive high quality care – and in making the best use of clinical time and NHS resources in all care.

Attention deficit hyperactivity disorder (ADHD) is a chronic, neurodevelopmental disorder associated with inattention, hyperactivity and impulsiveness. 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.

NICE NG87 states: Offer methylphenidate (either short or long acting) as the first line pharmacological treatment for children aged 5 years and over and young people with ADHD.

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 specialist provider.

Treatment must be under the supervision of an appropriate specialist in childhood, adolescent and/or adult behavioural disorders.

Methylphenidate is a mild central nervous system (CNS) stimulant.

#### 2. Licensed indications

Methylphenidate is indicated as part of a comprehensive treatment programme for attention deficit hyperactivity disorder in children and adolescents aged 6 years and

APC board date: 25 November 2020 | Last updated: Nov 2021 Shared Care Framework Review date: Nov 2023 (or earlier if there is significant new evidence relating to this recommendation) Version: 2.2 APC administration provided by Midlands and Lancashire Commissioning Support Unit

	over when remedial measures alone prove insufficient. Some brands of methylphenidate are also licensed to treat adults. Treatment must be under the supervision of a specialist in behavioural disorders.
3. Locally agreed off- label use	<ul> <li>This document supports the following off label uses:</li> <li>Continuation of treatment of ADHD 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 (brands not licensed for use in adults)</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>
4. Initiation and ongoing	Careful dose titration is necessary at the start of treatment and should always be

## 4. Initiation and ongoing dose regime

Careful dose titration is necessary at the start of treatment and should always be carried out under the supervision of the specialist.

Transfer of monitoring and prescribing to Primary care is after the dose has been stabilised and the patient has been reviewed by the specialist. The duration of treatment will be determined by the specialist based on clinical response and tolerability.

#### **Dosing information**

All dose adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.

Immediate-release preparations:

- 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).
- \*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.

Modified-release preparations:

- 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.
  - Patients established on an immediate-release methylphenidate hydrochloride formulation may be switched to the equivalent daily dose of a modified-release formulation

The dose should be titrated against symptoms and adverse effects in line with the BNF or BNF for Children until dose optimisation is achieved, that is, reduced symptoms, positive behaviour change, improvements in education, employment and relationships, with tolerable adverse effects.

#### Ongoing prescribing

Shared Care may only be commenced following initiation, stabilisation and review of treatment. In addition, formal agreement must have been received from the primary care prescriber. Termination will be the responsibility of the specialist.

 Review the use of Methylphenidate at least once a year and discuss with the patient (and their families and carers as appropriate) whether medication should be continued. (NICE NG87)

Supporting information	
	<ul> <li>Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. (NICE NG87)</li> </ul>
5. Baseline	Baseline: - Pre-treatment screening
investigations, initial monitoring, and dose	Before starting medication for ADHD, a full assessment should be completed which should include:
titration to be undertaken by	<ul> <li>a review to confirm they continue to meet the criteria for ADHD and need treatment</li> </ul>
specialist	a review of mental health and social circumstances, including:     presence of coexisting mental health and neurodevelopmental.

- presence of coexisting mental health and neurodevelopmental conditions
  - o current educational or employment circumstances
  - o risk assessment for substance misuse and drug diversion
  - o care needs
- a review of physical health, including:
  - a medical history, taking into account conditions that may be contraindications for specific medicines
  - current medication
  - height and weight (measured and recorded against the normal range for age, height and sex)
  - o baseline pulse and blood pressure
  - A cardiovascular assessment.

An electrocardiogram (ECG) is not needed before starting methylphenidate, unless the person has any of the features mentioned in recommendation 1.7.5 of the NICE 2018 Attention deficit hyperactivity disorder diagnosis and management guidelines or a co-existing condition that is being treated with a medicine that may pose an increased cardiac risk.

Refer to a paediatric hypertension specialist before starting medication for ADHD if blood pressure is consistently above the 95th centile for age and height for children and young people

## 6. Ongoing monitoring requirements to be undertaken by primary care

Monitoring	Frequency
Blood pressure and pulse (appropriate for age, using information supplied in attached request letter – children & adolescents only)	At every adjustment of dose or specialist 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 or at least every 6 months Primary care – every 6 months Weight every 3 months in children 10 years and under
Side effects	Every 6 months
Compliance	Every 6 months
Clinical need, benefits, side effects	Annual review by Specialist

Cardiovascular monitoring (blood pressure and heartrate) should be undertaken before and after each dose adjustment.

Refer to 'Adverse Drug Reactions' section for advice and actions to be taken.

Route of administration:	Oral
--------------------------	------

7.	<b>Pharmaceutical</b>		
	aspects		

#### 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

#### Administration details:

- 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 swallowed 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 are 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
- 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.		
9. Significant drug interactions	For a comprehensive list consult the BNF or Summary of Product Characteristics		
10. Adverse effects and management	For a comprehensive list consult the BNF or Summary of Product Characteristics.  In children, parents/patients will have been advised by the ADHD specialist to report any suspected side effects directly to them. GPs should refer any children with suspected side effects to the ADHD specialist irrespective of the advice in the following table.  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.		
	Adverse effect	Management	
	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 reductions 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 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. Discontinue or switch 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 test for confirmation. Seek initiating specialist advice if the adverse effect is secondary to the drug.	

#### Supporting information

		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 (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. 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.	
11. Advice to patients and carers	The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual drugs.		
	It is advisable for patients to abstain from alcohol during treatment. Alcohol can worsen the side effects of methylphenidate.		
	The patient should be advised to report any signs or symptoms suggestive of cardiac or psychiatric disorders or seizures to their GP without delay		
	In children, parents/patients will have been advised by the ADHD specialist to report the above signs or symptoms directly to them.		
12. Pregnancy and breastfeeding	Seek specialist advice for prescribing decision.		
13. Specialist contact information	If stopping medication or require advice. Please refer to the shared care agreement appendix 2		
14. Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.		
15. References	Summaries of product characteristics for methylphenidate SPC     NICE guidelines (NG87) February 2018: Attention deficit hyperactivity disorder: diagnosis and management <a href="https://www.nice.org.uk/guidance/ng87">https://www.nice.org.uk/guidance/ng87</a> NICE CKS for ADHD <a href="https://cks.nice.org.uk/attention-deficit-hyperactivity-disorder">https://cks.nice.org.uk/attention-deficit-hyperactivity-disorder</a> British National Formulary <a href="https://cks.nice.org.uk/attention-deficit-hyperactivity-disorder">BNF</a> British National Formulary for Children <a href="https://cks.nice.org.uk/attention-deficit-hyperactivity-disorder">BNF</a> British National Formulary for Children <a href="https://cks.nice.org.uk/attention-deficit-hyperactivity-disorder">https://cks.nice.org.uk/attention-deficit-hyperactivity-disorder</a>		
16. To be read in conjunction with the following documents	<ul> <li>Policy for shared care (Appendix 1)</li> <li>Shared care agreement (Appendix 2)</li> <li>RMOC Shared Care for Medicines <u>Guidance</u></li> <li>NHSE/NHSCC guidance – items which should not be routinely prescribed in primary care: guidance for CCGs <u>NHSE 2019</u></li> <li>NHSE policy- Responsibility for prescribing between Primary &amp; Secondary/Tertiary Care <u>NHSE</u></li> </ul>		

#### **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.

- Prescribing responsibility will only be transferred when the specialist and the patient's GP agree that the patient's condition is stable.
- Before prescribing responsibilities are transferred to primary care, 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 obtain patient informed consent for sharing of care between the specialist, primary care prescriber and patient. Consenting parties must have sufficient, accurate, timely information in an understandable form. Consent must be given voluntarily and must be documented in the patient's notes. Patients should be aware that shared care will not always be the best option for them. This is a mutual agreement between the specialist and primary care, which needs to be confirmed with the shared care agreement.
- To confirm the diagnosis.
- To confirm that the patient's care can be suitably maintained by primary care, following their medicine being optimised for approximately 3 months, with satisfactory investigation results.
- To initiate the medicine, prescribe, and monitor for toxicity and efficacy as described by the shared care framework until the patient is stabilised.
- To ensure the patient or their carer:
  - o Is counselled with regard to the risks and benefits of the medicine.
  - Is provided with any necessary written information with regard to the individual medicine including patient information leaflets on individual drugs.
  - Provides informed consent when any medicine 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.
- Following the request to the patient's GP to initiate shared care; to ensure that the patient has an adequate supply of medication (usually 28 days) until shared care arrangements are in place. Further prescriptions will be issued if, for unforeseen reasons, arrangements for shared care are not in place at the end of 28 days. Patients should not be put in a position where they are unsure where to obtain supplies of their medication.
- To assess the patient regularly as necessary for the duration of therapy. The specialist will send a written summary within 14 days to the patient's primary care prescriber, confirm that ongoing treatment with the monitored medicine is appropriate and record test results on the patient-held monitoring booklet if applicable confirm the current dosage and clearly highlight any changes made both to the patient and in writing to the patient's primary care prescriber.

The specialist team will:

#### Supporting information

- o provide training, advice, and guidance (as appropriate) for primary care prescribers if necessary to support the shared care agreement
- o provide contact details for both working and non-working hours
- o supply details for fast-track referral back to secondary/specialist care
- o provide the patient with details of their treatment, follow up appointments, monitoring requirements and, where appropriate, nurse specialist contact details
- To review the patient promptly if required by the GP.
- To meet any additional requirements as required by the individual medicine shared care framework.
- To communicate the 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.
- Prior to transfer of prescribing, the specialist will ensure that patients (and their caregivers, where
  appropriate) are aware of and understand their responsibilities to attend appointments and the need for
  continued monitoring arrangements.

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

- To prescribe within their own level of competence.
- 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 prescribe, 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 Snomed code "268529002
  Shared Care- Specialist/GP" can be used. Where applicable, keep the patient-held monitoring record up
  to date with the results of investigations, changes in dose and alterations in management.
- To be familiar with the individual shared care framework, have the information and knowledge to understand the therapeutic issues relating to the patient's clinical condition and undergo any additional training if necessary.
- To report any adverse effect in the treatment of the patient to the specialist team, and via the MHRA Yellow Card Scheme https://yellowcard.mhra.gov.uk/.
- 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 or monitoring covered by the shared care agreement.
- Where community nurse involvement is required in the administration of medicines under a shared care
  framework, nurses should be provided with adequate information and guidance by the prescriber or the
  specialist. Arrangements should be made in good time for any potential problems to be resolved to ensure
  that patient care is not compromised

Where the GP wishes to withdraw prescribing, for example when the patient fails to attend for monitoring, they need to give the specialist team a minimum of 14 days' notice of their need to resume responsibility for prescribing. The specialist is required to acknowledge this request within the 14-day time period.

#### **Patient Responsibilities in Shared Care**

- To provide their informed consent for sharing of their care with the specialist and primary care prescriber.
   Consenting parties must have sufficient, accurate, timely information in an understandable and accessible format. Consent must be given voluntarily and must be documented in the patient's notes. Supporting information is available from NICE Making decisions about your care
- To take their medication as agreed, unless otherwise instructed by an appropriate healthcare professional.
- To meet all necessary monitoring arrangements to ensure the safe prescribing of their medication, and to alert the prescriber where these arrangements are not met.
- To attend all follow-up appointments with the primary care prescriber and specialist. If the patient is unable to attend any appointments, they should inform the relevant practitioner as soon as possible and arrange an alternative appointment.
- Inform healthcare professionals of their current medications, both prescribed and purchased elsewhere prior to receiving any new prescribed or over-the-counter medication.
- Report all suspected adverse reactions to medicines to their primary care prescriber.
- Store their medication securely away from children and according to the medication instructions.
- Read the information supplied by their primary care prescriber, specialist and pharmacist and contact the relevant practitioner if they do not understand any of the information given.

#### **Appendix 2**

#### Shared Care Request letter (Specialist to Primary Care Prescriber)

Request by specialist clinician for the patient's GP to enter into a shared care agreement

To be signed by consultant / prescribing member of specialist team (circle or underline as appropriate)

Dear [insert Primary Care Prescriber's name]

Patient name: [insert patient's name]

Date of birth: [insert date of birth]

NHS Number: [insert NHS Number]

Diagnosis: [insert diagnosis]

Please add patient addressograph here

As per the agreed Pan Mersey APC shared care framework for [insert medicine name and dose] for the treatment of [insert indication], this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The risks and benefits of treatment have been explained to the patient	Yes / No
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	Yes / No
A copy of the shared care framework which covers this treatment/the shared care framework can be found here (insert electronic/ web link)	Yes / No
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

If you have provided supporting information to the patient, please insert a copy here

Treatment was started on [insert date started] and the current dose is [insert dose and frequency].

If you are in agreement, please undertake monitoring and treatment from [insert date] NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on [insert date] and should be continued in line with the shared care guideline.

Frequency of blood test:

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.

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.

Supporting information

#### **Details of Specialist Clinicians**

Name	Date
Consultant / prescribing member of specialist team (circle or u	underline as appropriate)
Signature	
In all cases, please also provide the name and contact details of	of the Consultant.
When the request for shared care is made by a prescriber who who takes medico-legal responsibility for the agreement.	o is not the specialist, it is the supervising consultant
Consultant:	
Contact details	
Telephone number:	Ext:
Address for return of documentation	

#### **Shared Care Agreement Letter (Primary Care Prescriber to Specialist)**

#### **Primary Care Prescriber Response**

Dear [insert Doctor's name]

Patient [insert Patient's name]

NHS Number [insert NHS Number]

Identifier [insert patient's date of birth and/or address]

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & Frequency

I can confirm that I am willing to take on this responsibility from [insert date] and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Usual (	GP signature:	Date
Usual (	GP name:	(please print)
GP:	: Please sign and return a copy within 21 calendar days to the address above	
GP Practice address/practice stamp		

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