This policy statement is approved by Halton, Knowsley, Liverpool, St Helens, Warrington, and West Lancashire CCGs

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NHS
Pan Mersey
Area Prescribing Committee

SHARED CARE FRAMEWORK

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

SHARED CARE

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

Background

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 initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist or psychiatrist.

Mode of action

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

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 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.

Locally agreed off-label use

This document supports the following off label uses:

- Continuation of treatment of ADHD 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 (brands not licensed for use in adults)
- Treatment of ADHD in children under 6 years (exceptional use)
- 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.

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)

- 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)

Baseline investigations, initial monitoring and dose titration to be undertaken by specialist

Baseline: - Pre-treatment screening

Before starting medication for ADHD, a full assessment should be completed which should include:

- a review to confirm they continue to meet the criteria for ADHD and need treatment
- a review of mental health and social circumstances, including:
  - presence of coexisting mental health and neurodevelopmental conditions
  - current educational or employment circumstances
  - risk assessment for substance misuse and drug diversion
  - 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)
  - 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

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 heart rate) should be undertaken before and after each dose adjustment.

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

Pharmaceutical aspects

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

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.

Contraindications

For a comprehensive list consult the BNF or Summary of Product Characteristics

Significant drug interactions

For a comprehensive list consult the BNF or Summary of Product Characteristics

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. 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.

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.

Pregnancy and breast feeding

Seek specialist advice for prescribing decision.

Specialist contact information

See appendix 2

Additional information

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.

References

1. Summaries of product characteristics for methylphenidate

2. NICE guidelines (NG87) February 2018: Attention deficit hyperactivity disorder: diagnosis and management https://www.nice.org.uk/guidance/ng87

3. NICE CKS for ADHD https://cks.nice.org.uk/attention-deficit-hyperactivity-disorder

4. British National Formulary

5. British National Formulary for Children

To be read in conjunction with the following documents.

1. Policy for Shared Care
2. Shared care agreement.

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.

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.

Shared Care Framework

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.

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.

Appendix 2

Shared Care Agreement

Disease modifying drugs (DMDs)

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 _____

Dear Dr_____

I request that you prescribe

METHYLPHENIDATE

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 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:_____

Shared Care Framework

Address for return _____

of documentation

_____

_____

Please add patient addressograph here

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: