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National Shared Care Protocol: NHS South Yorkshire (Rotherham) & RDaSH

# Methylphenidate in Adult Services

4 July 2022 (Version 1 – National), 1 June 2024 (Version 3b – LMC copy)

Review date - April 2027

The content of this shared care protocol was correct as of April 2024. As well these protocols, please ensure that <u>summaries of product characteristics</u> (SPCs), <u>British national formulary</u> (BNF) or the <u>Medicines and Healthcare products Regulatory Agency</u> (MHRA) or <u>NICE</u> websites are reviewed for up-to-date information on any medicine.

### **Specialist responsibilities**

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable the patient to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5.
- Prescribe the maintenance treatment for at least 3 months or until optimised.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Once treatment is optimised, complete SCP proforma and send to patient's GP practice detailing the diagnosis, brand to be prescribed, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication (at least ONE months) to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in section 8 and communicate the results to primary care.
- Ensure patient receives a review, at least annually, with ADHD specialist.

- After each review, advise primary care if patient remains suitable for Shared Care and whether treatment should be continued, confirm the stabilised dose.
- Trial discontinuations (i.e. holidays) should be managed by the specialist.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Reply to requests for advice from primary care within a timely manner (e.g. 48 hours)
- Prescribing responsibility will return to the specialist (within 28 days) if patient deemed no longer suitable for shared care by either primary care (via Appendix 3) or secondary care.

### **Primary care responsibilities**

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 5, taking into account any potential drug interactions in section 7.
- Prescribe in line with controlled drug 28 day prescription requirements (section 6).
- Perform medicines reconciliation following dose modification and stabilisation by Specialist
- Conduct the required monitoring as outlined in section 9.
- Communicate issues arising from monitoring to the Specialist (where necessary)
- Be aware for possible interactions with methylphenidate when starting new medicines (see section 7).
- Be aware of any adverse effects as detailed in section 10 and signpost to specialist team.
- Stop methylphenidate and make an urgent referral for appropriate care if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected.
- Refer management back to the specialist if the patient becomes/plans to become pregnant.
- Stop treatment as advised by the specialist.

### Patient and/or carer responsibilities

- Take methylphenidate as prescribed, and avoid abrupt withdrawal unless advised by their prescriber.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects directly to their ADHD specialist. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications (OTC) to their primary care prescriber and be aware they should discuss the use of methylphenidate with their pharmacist before purchasing any OTC medicines.
- Not to drive or operate heavy machinery if methylphenidate affects their ability to do so safely, and inform the DVLA if their ability to drive safely is affected (see section 11).

- Avoid alcohol during treatment, as it may make some side effects worse. Avoid recreational drugs.
- Methylphenidate is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store methylphenidate safely and securely. It must not be shared with anyone else.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

### 1. Background

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Methylphenidate is a central nervous system stimulant licensed as part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD). It may be offered as a first line pharmacological treatment option for adults with ADHD who have been appropriately diagnosed (see NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management). NICE recommends that people with ADHD have a comprehensive, holistic shared treatment plan that addresses psychological, behavioural and occupational or educational needs.

Methylphenidate is available as immediate-release tablets, and modified-release tablets and capsules. The modified-release preparations contain both immediate-release and prolongedrelease methylphenidate, and different brands have different proportions of each. Brands may therefore vary in their release characteristics and clinical effect. Modified-released preparations should therefore be prescribed by brand name.

Methylphenidate is a schedule 2 controlled substance; all legal requirements for prescribing controlled drugs should be followed. See NICE Guidance NG46 Controlled drugs: safe use and management. Risk of misuse can be reduced by using modified-release preparations. Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the

appropriate adult service if need for ongoing treatment is anticipated.

The safety and efficacy of long-term use of methylphenidate has not been systematically evaluated in controlled trials. Patients should be reviewed for ongoing need at least annually, and the manufacturers recommend a trial discontinuation at least once yearly to assess the patient's condition.

Methylphenidate is not licensed for all the indications it is used to treat below. However, its use for the indications below are established and supported by various sources and bodies including the BNF and NICE.

### 2. Indications

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Attention deficit hyperactivity disorder (ADHD) in adults (RDaSH)

Narcolepsy<sup>†</sup> (Neurology)

### 3. Locally agreed off-label use

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To be agreed and completed locally (include supporting information)

Narcolepsy (separate Neurology SCP)

#### 4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see **BNF** & **SPC** for comprehensive information.

#### **Contraindications:**

- Hypersensitivity to methylphenidate or to any of the excipients
- Glaucoma
- Phaeochromocytoma
- During treatment with non-selective, irreversible monoamine oxidase (MAO) inhibitors, or within a minimum of 14 days of discontinuing those drugs, due to the risk of hypertensive crisis
- Hyperthyroidism or thyrotoxicosis
- Diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder.
- Diagnosis or history of severe and episodic (Type I) bipolar (affective) disorder (that is not well-controlled).
- Certain pre-existing cardiovascular disorders constitute contraindications unless specialist cardiac advice is obtained and documented. These include severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias, disorders caused by the dysfunction of ion channels, and structural cardiac abnormalities.
- Pre-existing cerebrovascular disorders cerebral aneurysm, vascular abnormalities including vasculitis or stroke.
- Medikinet XL only: history of pronounced anacidity of the stomach with a pH value above 5.5, or during therapy with H2 receptor blockers, proton pump inhibitors or antacids.

#### Cautions:

- Family history of sudden cardiac or unexplained death, malignant arrhythmia.
- Cardiovascular status should be carefully monitored (see section 9 & section 10)
- Underlying conditions which might be compromised by increases in blood pressure or heart rate.

<sup>&</sup>lt;sup>‡</sup> Off-label indication. Please note licensed indications vary by manufacturer; see SPC for full <u>details</u>. Some brands are not licensed in adults (see <u>section 6</u>)

- Known drug or alcohol dependency or misuse of central nervous system (CNS) stimulants: potential for abuse, misuse or diversion.
- Alcohol consumption (not recommended during treatment)
- Epilepsy: may lower seizure threshold
- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, depressive symptoms, bipolar disorder.
- Renal or hepatic insufficiency (due to lack of data)
- Leukopenia, thrombocytopenia, anaemia, or other haematological abnormalities.
- Prolonged-release tablets only: severe narrowing of the gastrointestinal tract or dysphagia; risk of obstruction
- Safety and efficacy has not been established in patients older than 60 years of age.
- Susceptibility to open-angle glaucoma.
- Pregnancy or breast-feeding (see section 12)
- Potential for abuse, misuse, or diversion.

### 5. Initiation and ongoing dose regimen

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- Methylphenidate **must** be prescribed by specialist during initiation & dose stabilisation.
- Transfer of monitoring and prescribing to primary care is normally after at least 3 months (or later once dose stable), and with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

#### Initial stabilisation:

#### Recommended starting dose in ADHD:

- <u>Immediate release tablets</u>: 5 mg, given 2-3 times daily
- Modified release tablets: 18 mg daily, given in the morning
- Modified release capsules: 10-20 mg daily

Adults with ADHD who have shown clear benefit from methylphenidate in childhood or adolescence may continue treatment into adulthood at the same daily dose. Consult SPC for the prescribed brand for more information.

#### Maintenance dose (following initial stabilisation):

The dose of methylphenidate should be titrated to response, usually at weekly intervals.

#### Maximum dose in ADHD:

- Immediate release tablets: up to 100 mg daily in 2-3 divided doses
- Modified release tablets: up to 108 mg once daily, given in the morning

• Modified release capsules: up to 100 mg daily. May be given as a single dose in the morning or in divided doses in the morning and at midday, depending on brand.

The maximum licensed daily dose varies with formulation and brand; consult **BNF** and **SPC**.

#### **Conditions requiring dose adjustment:**

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. This should be undertaken and supervised by the specialist who will advise the patient and primary care prescriber of the outcome.

6. Pharmaceutical aspects  Back to to			
Route of administration:	Oral		
Formulation:	Methylphenidate hydrochloride.  Standard release tablets:  Methylphenidate hydrochloride (generic): 5mg, 10mg, 20mg  Medikinet®: 5mg, 10mg, 20mg  Ritalin®: 10mg		
Green = Preferred	Tranquilyn®: 5mg, 10mg, 20mg  NB: Brand name prescribing is not necessary for standard release tablets.		
Amber = Alternative	Prolonged-release tablets *:  NB: Modified-released preparations vary in their release characteristics and must be prescribed by brand name. The specialist must specify the brand to be		
Red = Non- preferred	prescribed. Affenid XL®: 18mg, 27mg, 36mg, 54mg Concerta XL®: 18mg, 27mg, 36mg, 54mg		
branded generics  Affenid, Delmosart	Delmosart XL®: 18mg, 27mg, 36mg, 54mg  Matoride XL®: 18mg, 36mg, 54mg		
XL, Matoride XL, Xaggitin XL and	Xaggitin XL®: 18mg, 27mg, 36mg, 54mg Xenidate XL®: 18mg, 27mg, 36mg, 54mg		
Xenidate XL all have equivalent release profiles	NB: Methylphenidate prolonged-release tablets are licensed for continuation in adults who have shown clear benefit from treatment in childhood and/or adolescence. They are not licensed for intiation in		
and are considered interchangeable.  Alternative	adults. Use in this way is considered off-label.  Modified-release capsules:		

Non-	pre	ferr	ed

NB: Modified-released preparations vary in their release characteristics and must be prescribed by brand name. The specialist must specify the brand to be prescribed.

Equasym XL®: 10mg, 20mg, 30mg

Medikinet XL® ▼: 5mg, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg

Meflynate XL®: 10mg, 20mg, 30mg, 40mg, 60mg Metyrol XL®: 10mg, 20mg, 30mg, 40mg, 60mg Ritalin XL®: 10mg, 20mg, 30mg, 40mg, 60mg

NB: Ritalin XL and Medikinet XL modified-release capsules are licensed for initiation and continuation in adults.

Equasym XL is not licensed for use in adults

Please consult the relevant **SPC** for brand-specific licensing information.

### Administration details:

Methylphenidate can be taken with or without food, but patients should standardise which method is chosen.

Administration requirements vary by formulation and brand. Methylphenidate capsules can be opened and sprinkled on a small amount of soft food for administration. Please consult the relevant SPC for brand-specific information. If a dose is missed then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose.

### Other important information:

Methylphenidate is a schedule 2 controlled drug and is subject to legal prescription requirements. It has the potential for misuse and diversion. The choice of formulation will be decided by the treating specialist on an individual basis, and depends on the intended duration of effect. Risk of misuse can be reduced by using modified-release preparations.

Alcohol may exacerbate CNS adverse effects of methylphenidate and should be avoided during use.

Methylphenidate may cause false positive laboratory test results for amphetamines.

### 7. Significant medicine interactions

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The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

- Monoamine oxidase inhibitors (MAOIs): risk of hypertensive crisis. The combination should be avoided, and use of methylphenidate and MAOIs should be separated by at least 14 days
- Coumarin anticoagulants, anticonvulsants (e.g. phenobarbital, phenytoin, primidone), selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants:

metabolism may be inhibited by methylphenidate. Dose adjustment may be required when starting or stopping methylphenidate.

- Anti-hypertensive drugs: effectiveness may be reduced by methylphenidate
- Other drugs which elevate blood pressure: risk of additive effects (e.g. linezolid)
- Alcohol: may exacerbate adverse CNS effects of methylphenidate
- **Serotonergic drugs**, including SSRIs and MAOIs: increased risk of central nervous system (CNS) adverse effects, risk of serotonin syndrome
- Halogenated anaesthetics: risk of sudden blood pressure increase during surgery. Avoid methylphenidate on the day of planned surgery.
- **Dopaminergic drugs**, **including antipsychotics**: increased risk of pharmacodynamic interactions including dyskinesias or hypertensive crisis (e.g. risperidone, paliperidone, selegiline, rasagiline)
- **Apraclonidine:** effects decreased by methylphenidate.
- Carbamazepine: may decrease methylphenidate levels
- **Ozanimod:** may increase risk of hypertensive crisis

#### 8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by SPECIALIST Back to top

Monitoring at baseline and during initiation is the responsibility of specialist. Only once patient is optimised (at least 3 months) on chosen medication with no anticipated further changes expected (until at least next annual review) will prescribing and monitoring request to primary care be made.

#### **Baseline investigations:**

- A medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required
- Risk assessment for substance misuse and drug diversion
- Height, weight, and body mass index (BMI)
- Blood pressure (BP) and heart rate
- Arrange for electrocardiogram (ECG), only if the patient has any of the following:
  - History of congenital heart disease or previous cardiac surgery
  - Sudden death in a first-degree relative under 40 years suggesting a cardiac disease
  - Shortness of breath on exertion compared with peers
  - o Fainting on exertion or in response to fright or noise
  - Palpitations
  - Chest pain suggestive of cardiac origin
  - Signs of heart failure, heart murmur or hypertension
  - Current treatment with a medicine that may increase cardiac risk

#### **Initial monitoring:**

- Before every change of dose: assess heart rate, blood pressure, and weight.
- After every change of dose: assess heart rate & blood pressure, and any new or worsening psychiatric symptoms. Specialist should determine appropriate timing for this monitoring.
- Assessment of symptom improvement: discontinue if no improvement seen after 1 month.

#### Ongoing monitoring (ADHD):

- Ensure patient receives a review, at least annually, with ADHD specialist. (this must be in secondary care by a specialist who is a prescriber or under a prescriber's supervision).
- Should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need.
- Consider trial periods of stopping medication (e.g. treatment holidays) or reducing the dose/frequency (e.g. weekends/off school or work) when assessment of the overall balance of benefits and harms suggests this may be appropriate.
- If continuing medication, document the reasons why.
- Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone.
- Respond to patient contacts re side-effects / concerns

### 9. Ongoing monitoring requirements to be undertaken by PRIMARY CARE

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
Blood Pressure and Heart Rate     (and rhythm assessment)	Every 6 months
Weight     (and appetite if loosing weight)	
Check patient has been offered and attended an annual review at RDaSH Adult ADHD Clinic	Annually (by letter notification)

If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

### 10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

### Result Action for primary care As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance. Cardiovascular In context of recent dose increase, revert Resting HR greater than 120bpm, to previous dose and discuss with arrhythmia/palpitations, clinically significant specialist for on-going management increase in systolic BP In absence of recent dose changes, discuss with Specialist (or cardiology for further advice) Weight or BMI outside healthy range, Exclude other reasons for weight loss. Give anorexia or weight loss advice as per NICE NG87: take medication with or after food, not before additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off obtaining dietary advice consuming high-calorie foods of good nutritional value **Discuss with Specialist** if difficulty persists; dose reduction, treatment break, or change of medication may be required. Haematological disorders Discontinuation should be considered. Advice Including leukopenia, thrombocytopenia, & Guidance or referral to haematology may be anaemia or other alterations warranted; use clinical discretion. NB: no haematological monitoring is recommended. Haematological disorders Inform ADHD Specialist. would be a chance finding/due to patient reporting adverse drug reactions.

Psychiatric disorders  New or worsening psychiatric symptoms, e.g. psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, bipolar disorder, depression.	Signpost patient to ADHD Specialist.  Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present Methylphenidate should not be continued unless the benefits outweigh the risks.
Nervous system disorders Symptoms of cerebral ischaemia, e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory	Discontinue methylphenidate, refer urgently for neurological assessment.  Inform ADHD specialist.
New or worsening seizures	Signpost patient to ADHD Specialist. and/or Epilepsy Service (if under)
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue methylphenidate as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary.  Inform ADHD specialist.
Insomnia or other Sleep disturbance	Give advice on sleep hygiene.  Signpost patient to ADHD Specialist if difficulty persists; dose reduction may be required.
Suspicion of abuse, misuse, or diversion	Inform ADHD specialist.

## 11. Advice to patients and carers

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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 medicines.

The Patient should be advised to report any of the following signs or symptoms to their SPECIALIST without delay:

Abnormally sustained or frequent and painful erections: seek immediate medical attention.

- Signs or symptoms of serotonin syndrome (e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea)
- Any mood changes, for example. psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety, agitation or tension, anxiety, depression
- New or worsening neurological symptoms (e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory)
- Abdominal pain, malaise, jaundice or darkening of urine
- Skin rashes, or bruising easily
- If they suspect they may be pregnant, or are planning a pregnancy. Patients of childbearing potential should use appropriate contraception, and take a pregnancy test if they think there is a possibility they could be pregnant.

#### The patient should be advised:

For non-pharmacological support, please refer &/or signpost people to Rotherham Adult Neurodiversity Support Service (RANSS) RANSS is a peer support service for people with an ASD or ADHD diagnosis. https://yourhealthrotherham.co.uk/wp-content/uploads/2023/12/RANSS-booklet-for-practitioners-3.pdf

- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. It may not be safe to continue prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments.
- Not to drive or operate machines if methylphenidate affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or visual disturbances.
- People who drive must inform the DVLA if their ADHD, narcolepsy or medicines affect their ability to drive safely. See https://www.gov.uk/adhd-and-driving or https://www.gov.uk/narcolepsy-and-driving.
- Avoid alcohol while taking methylphenidate, as it may make side effects worse. Avoid recreational drugs.
- Not to stop taking methylphenidate without talking to their doctor. Medical supervision of withdrawal is required, since this may unmask depression or chronic over-activity.
- Methylphenidate is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions, and should store methylphenidate safely and securely. It must not be shared with anyone else. There are restrictions on travelling with controlled drugs: see https://www.gov.uk/guidance/controlled-drugs-personal-licences.

#### Patient information:

Royal College of Psychiatrists – ADHD in adults. https://www.rcpsych.ac.uk/mental-health/problemsdisorders/adhd-in-adults

- NHS Attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficithyperactivity-disorder-adhd/
- Narcolepsy UK methylphenidate. <a href="https://www.narcolepsy.org.uk/resources/methylphenidate">https://www.narcolepsy.org.uk/resources/methylphenidate</a> NHS - Narcolepsy. https://www.nhs.uk/conditions/narcolepsy/

### 12. Pregnancy, paternal exposure and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

#### **Pregnancy:**

Methylphenidate is not recommended for use during pregnancy unless a clinical decision is made that postponing treatment may pose a greater risk to the pregnancy.

Evidence on exposure to methylphenidate during pregnancy is too limited to draw firm conclusions on adverse outcomes. Clinicians should be aware that patients may have other risk factors which independently alter the risks.

Patients who become pregnant while taking methylphenidate, or who plan a pregnancy, should be referred to the specialist team for review. The specialist will reassume prescribing responsibility, ending the shared care agreement.

Healthcare professional information available from:

https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-METHYLPHENIDATE-IN-PREGNANCY/

Patient information available from: <a href="https://www.medicinesinpregnancy.org/Medicine---">https://www.medicinesinpregnancy.org/Medicine---</a> pregnancy/Methylphenidate/

#### **Breastfeeding:**

Methylphenidate has been found in breast milk in small amounts. Evidence for safety in breastfeeding is limited. Decisions to use while breastfeeding should be made on a case-bycase basis, taking into account the risks to the infant and benefits of therapy. Infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite/weight gain, sleep disturbances, irritability), although these may be difficult to detect. High doses may interfere with lactation, although this is not confirmed in practice.

Healthcare professional information available from: https://www.sps.nhs.uk/articles/safety-inlactation-drugs-for-adhd/

#### Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified.

Further information for patients: bumps - best use of medicine in pregnancy (medicinesinpregnancy.org)

## 13. Specialist contact information (also for patients)

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Name: Sadie Watkinson-North

Role and specialty: Clinic Lead / Nurse Consultant

Daytime telephone number: 03000 215 805

Email address: rdash.rotherhamadultsadhd@nhs.net

Alternative contact: N/A

Out of hours contact details: N/A

#### **Additional information** 14.

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References Back to top

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- NICE. NG46: Controlled drugs: safe use and management. April 2016. Accessed via https://www.nice.org.uk/guidance/ng46/ on 05/05/2021
- Methylphenidate (MPH): physician's guide to prescribing. Accessed via http://www.methylphenidate-guide.eu/gb/welcome.php on 14/04/21
- Evidence-based guidelines for the pharmacological management of attention deficit hyperactivity disorder: Update on recommendations from the British Association for Psychopharmacology. Bolea-Alamañac B, Nutt DJ, Adamou M, et al. Journal of Psychopharmacology. 2014. 1–25. DOI: 10.1177/0269881113519509
- UKTIS. Use of methylphenidate in pregnancy. Last updated January 2018. Accessed via https://www.toxbase.org/poisons-index-a-z/m-products/methylphenidate-in-pregnancy/on 14/04/2021

- Specialist Pharmacy Service. Safety in Lactation: Drugs for ADHD. Last updated October 2020. Accessed via https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/ on 05/05/2021
- Specialist Pharmacy Service. Methylphenidate Lactation Safety Information. Last updated September 2018. Accessed via https://www.sps.nhs.uk/medicines/methylphenidate/ on 05/05/2021

### 16. Other relevant national guidance

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- Shared Care for Medicines Guidance A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/
- NHSE guidance Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-betweenprimary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethicalguidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-anddevices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

### 17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Electronic letters.

NHS South Yorkshire (Rotherham Place) MMC date: 17/04/24 RDaSH MMC date: 19/04/24 LMC update Sept 2024

## **Appendix 1: Shared Care "Request" Letter** (Specialist to Primary Care Prescriber)

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]

As per the agreed NHS SY/RDasH for Methylphenidate for treatment of Adult ADHD 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.

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

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	Yes / No
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	Yes / No
The risks and benefits of treatment have been explained to the patient	Yes / No
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	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
The patient has been referred/signposted to Rotherham Adult Neurodiversity Support Service (RANSS)	Yes / No
I have included with the letter copies of the information the patient has received	Yes / No
I have provided the patient with sufficient medication to last until	At least 28 days
I have arranged a follow up with this patient in the following timescale	At least 12 months

Treatment started on [insert date started] & current dose [insert dose and frequency].

If you are in agreement, please undertake treatment from [insert date]

NB: date must be at least 1 month from initiation of treatment.

Next monitoring as per SCP is due on [insert date]

NB: date must be at least 6 month from initiation of treatment.

Please respond to this request for shared care within 14 days of the request (where possible)

# **Appendix 2: Shared Care "Agreement" Letter** (Primary Care Prescriber to Specialist)

### **Primary Care Prescriber Response**

Dear	[insert D	octor's name]	
Patient	[insert Patient's name]		
NHS Number	[insert NHS Number]		
Identifier	[insert p	atient's date of birth and/ora	ddress]
	•	or me to accept prescribing rent and to provide the follow	• •
Medicine	Э	Route	Dose & frequency
	itoring as s	g to take on this responsibility set out in the shared care pro	
Primary Care Prescriber signature:			Date:
Primary Caro Proc	ecriber add	ress/practice stamp	
Filliary Gale Pies	SCHUEL ACIC	TESS/DIACTICE STATED	

Please return completed copy to: <a href="mailto:rdash.rotherhamadultsadhd@nhs.net">rdash.rotherhamadultsadhd@nhs.net</a>

## **Appendix 3: "Unable to Take / Continue" Shared Care** (Primary Care Prescriber to Specialist)

Re:

Patient [insert Patient's name] NHS Number [insert NHS Number]

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

Thank you for your request for me to accept prescribing responsibility for this patient.

In interest of patient safety NHS [insert CCG name], in conjunction with local acute trusts have classified [insert medicine name]as a Shared Care drug, and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

	Unable to "take" = 1 to 6	Tick
1.	The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care	
	I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.	
2.	The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement	
	Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you	
3.	A minimum duration of supply by the initiating clinician	
	Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.	
4.	Initiation and optimisation by the initiating specialist	
	Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.	

5.	Shared Care Protocol not received	
	Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.	
6.	Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)	
7	Patient NO longer suitable for Shared Care (please add reason)	
	[Prescribing responsibility to return to the specialist within 28 days]	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date info to individual GPs." In this case we would also see term GP being interchangeable with term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible.

Primary Care Prescriber signature:	
Date:	

**Primary Care Prescriber address/practice stamp** 

Please return completed copy to: rdash.rotherhamadultsadhd@nhs.net