Frimley Integrated Care Board (ICB)

Methylphenidate AMBER shared care protocol for Children and Young People aged 6 – 17 years
For use between Frimley ICB Primary Care and any Right to Choose (RTC) or Private Provider

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Methylphenidate

Methylphenidate is indicated as part of a comprehensive treatment programme for attention-deficit hyperactivity disorder (ADHD) in children aged 6 years of age and over when remedial measures alone prove insufficient. The decision to prescribe a stimulant must be based on rigorous assessment of the severity and chronicity of the child's symptoms in relation to the child's age.

A comprehensive treatment programme typically includes psychological, educational and social measures as well as pharmacotherapy and is aimed at stabilising children with a behavioural syndrome characterised by symptoms which may include chronic history of short attention span, distractibility, emotional lability, impulsivity, moderate to severe hyperactivity, minor neurological signs and abnormal EEG. Learning may or may not be impaired.

Treatment must be under the supervision of a specialist in childhood behavioural disorders. Diagnosis should be made according to DSM criteria or the guidelines in ICD-10 and should be based on a complete history and evaluation of the patient. Diagnosis cannot be made solely on the presence of one or more symptom.

The use of methylphenidate should always be used according to the licensed indication and according to prescribing/ diagnostic guidelines.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this 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 provide the appropriate counselling (see section 11) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- 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.
- Transfer to primary care is normally after the patient has been treated at the maintenance dose for 2 months and with satisfactory investigation results for at least 4 weeks. Prescribe sufficient medication (one month's supply) to enable transfer to primary care, including where there are unforeseen delays to transfer of care. Check product details for pack sizes as most products manufactured in boxes of 30 dose units.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Once treatment is optimised, complete the shared care documentation and send a request to prescribe to patient's GP practice detailing the diagnosis, current and ongoing dose, baseline and most recent test results, confirm the monitoring schedule and when the next monitoring is required. Include contact information (section 13).
- Conduct the required monitoring in section 8 and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- Reassume prescribing responsibilities if the patient becomes or wishes to become pregnant.
- If the patient develops a concurrent mental health or neurodevelopmental condition requiring specialist care where their ADHD is best managed by the specialist service, reassume prescribing responsibilities, or inform the patient's GP that a referral to an alternative provider is required in order to properly support the patient.
- Provide advice to primary care on the management of adverse effects if required.
- Advise primary care if treatment should be discontinued. Trial discontinuations can be supported by the specialist.

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 accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5 taking into any account potential drug interactions in section 7.
- Adjust the dose of methylphenidate prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9.
- Assess for possible interactions with methylphenidate when starting new medicines (see section 7).
- Manage any adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop methylphenidate and make an urgent referral to the specialist if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected.
- Discuss other adverse effects with the specialist team as clinically appropriate (section 10).
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.

Patient and/or carer responsibilities

- Not to drive, use other modes of transport that require a high level of alertness e.g. bicycle, scooter, operate machines or undertake skilled tasks if methylphenidate affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or visual disturbances
- Avoid alcohol while taking methylphenidate, as it may make side effects worse.

- Take methylphenidate as prescribed and do not stop taking it without speaking to their primary care prescriber or specialist. Medical supervision of withdrawal is required, since this may unmask depression or chronic over-activity.
- Methylphenidate is a schedule 2 controlled drug. Patients, their family or carer 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. Note that where a child (under 16) presents to a pharmacy to collect their medication, pharmacists will need to decide whether to provide it to them, or request that a family member or carer collects the medicine, based on the individual circumstances.
- Tell anyone who prescribes them a medicine that they are taking methylphenidate
- Attend regularly for monitoring and review appointments with primary care and specialist. Be aware that medicines may be stopped if they do not attend appointments.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications to their GP and be aware they should discuss the use of methylphenidate with their pharmacist before purchasing any OTC medicines.
- People of child-bearing potential should inform the specialist or GP immediately If they suspect they may be pregnant, or are planning a pregnancy

1. Background

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 children aged 5 years and over and young people 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 prolonged-release 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.

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

Where a person with ADHD is approaching their 18th birthday, it is expected that the provider will refer to the appropriate adult service if a need for ongoing treatment is anticipated. NICE Guidance

NG43 Transition from children's to adults' services for young people using health or social care services should be followed.

2. Indications

- Attention deficit hyperactivity disorder (ADHD) in children aged 6 years and over

3. Locally agreed off-label use

This shared care protocol only supports use of methylphenidate within its licensed indication. The following information should be provided in correspondence to support prescribing in line with this shared care.

- Dosing specific to the indication
- Relevant interaction information
- Any additional monitoring requirements over and above the shared care.
- Duration of treatment
- Frequency of review.
- Specific features of adverse effects or deterioration pertinent to the specific indication for which it is used

4. Contraindications and cautions

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.
- 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

- Transfer of monitoring and prescribing to primary care is normally between 8 - 12 weeks, and when the patient's dose has been optimised 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:

Immediate release tablets: 5 mg, given once or twice daily

Modified release tablets: 18 mg daily, given in the morning.

Modified release capsules: 10mg daily

Note that the modified-release preparations contain both immediate-release and prolonged-release 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.

The most cost effective medications within each category must be chosen unless there is a specific clinical reason stated. Formulary choices can be found here: Frimley ICS Medicines Optimisation Board Formulary

The stabilisation period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

The dose of methylphenidate should be titrated to response, usually at weekly intervals. Maximum dose in ADHD in children (check individual product SPC):

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 or divided doses, depending on brand.

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

The initial maintenance dose must be prescribed by the initiating specialist.

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, their family or carer, and GP of the outcome.

6. Pharmaceutical aspects

Route of administration	Oral
Formulation	Methylphenidate hydrochloride. Standard release tablets: Medikinet®: 5mg, 10mg, 20mg Methylphenidate hydrochloride (generic): 5mg, 10mg, 20mg Ritalin®: 10mg Tranquilyn®: 5mg, 10mg, 20mg Prescribe generically. Brand name prescribing is not necessary for standard release tablets. Prolonged-release tablets: NB: Modified-released preparations vary in their release characteristics and must be prescribed by brand name. Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to differences in formulations - GOV.UK. The specialist must specify the brand to be prescribed, using formulary choices: Frimley ICS Medicines Optimisation Board Formulary. In times of stock shortage it may be necessary to prescribe generically but this should be changed back to a preferred brand as soon as possible. The prolonged release tablets listed below are all bioequivalent. Affenid XL®: 18mg, 27mg, 36mg, 54mg Delmosart®: 18mg, 27mg, 36mg, 54mg Matoride XL®: 18mg, 36mg, 54mg Xaggitin XL®: 18mg, 27mg, 36mg, 54mg Xenidate XL®: 18mg, 27mg, 36mg, 54mg Concerta XL®: 18mg, 27mg, 36mg, 54mg Modified-release capsules:

	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 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	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, 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 prescribing restrictions and 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. Details of the release characteristics of the different formulations are given in a review document by the Specialist Pharmacy Services. 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

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

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future, will a transfer to primary care for prescribing and monitoring occur.

Pre-treatment (specialist):

- 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
- Pulse, BP
- Weight, Height, (use centiles in children), Appetite
- Psychiatric symptoms
- ECG (if history of congenital heart disease or previous cardiac surgery, sudden death in a first-degree relative under 40 years suggesting a cardiac disease, family history of CVD or arrhythmia, shortness of breath on exertion compared with peers, 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 (specialist):**

  - Assess heart rate and blood pressure after every change of dose
  - Weight and height (using centiles as per NICE)
  - Assessment for new or worsening psychiatric symptoms following every change of dose
  - Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Ongoing monitoring (ADHD):

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This will be by the specialist, as per local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. 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. 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.

9. Ongoing monitoring requirements to be undertaken by primary care

See section 10 for further guidance on management of adverse effects/responding to monitoring results.
Specialist clinician will monitor until primary care prescriber has agreed to take over prescribing.

Monitoring and actions	Frequency
Maintenance: • Height and weight and plot on a growth chart • Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms • Assessment for new or worsening psychiatric and neurological signs or symptoms • Assessment for any indication of abuse, misuse, or diversion, based on the patient's circumstances • Explore whether patient is experiencing any difficulties with sleep • In people of child-bearing potential, assess whether there is a risk of pregnancy. Consider pregnancy testing where appropriate • Review of ADHD medication, including preferences of the patient, their family or carer, benefits, adverse effects, and ongoing clinical need. Consider trial period off medication	• measure height every 6 months in children and young people • measure weight every 3 months in children 10 years and under • measure weight at 3 and 6 months after starting treatment in children over 10 years and young people, and every 6 months thereafter, or more often if concerns arise • Monitor heart rate and blood pressure and compare with the normal range for age before and after each dose change and every 6 months. • The specialist clinician will carry out the annual review • Do not offer routine blood tests (including liver function tests) or ECGs to people taking medication for ADHD unless there is a clinical indication.
• If dose change when on maintenance: • Pulse, BP • Weight, Height, (use centiles), Appetite • Psychiatric symptoms	Specialist clinician responsibility

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

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	Symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or other signs or symptoms suggestive of cardiac disease	Refer for urgent specialist cardiac evaluation
	Resting tachycardia >120 beats per minute, arrhythmia or systolic blood pressure greater than the 95th percentile (or a clinically significant increase) measured on 2 occasions	Reduce dose by half and refer to specialist for further advice
Weight or BMI	outside healthy range or falling off centiles, anorexia or weight loss	Exclude other reasons for weight loss. Give 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	Including leukopenia, thrombocytopenia, anaemia or other alterations	Contact specialist team. Discontinuation should be considered. Referral to haematology may be warranted; use clinical discretion
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	Discuss with 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 assessment
	New or worsening seizures	Discontinue methylphenidate. Refer to specialist team.
	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. Discuss with specialist team to determine whether methylphenidate can be re-started.
	Insomnia or other sleep disturbance	Review timing of methylphenidate dose and advise as appropriate. Give advice on sleep hygiene. Consider using a sleep diary Discuss with specialist if difficulty persists; dose reduction may be required.

Suspicion of abuse, misuse, or diversion	Discuss with specialist team

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 medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber 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:

- 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, use other modes of transport that require a high level of alertness eg bicycle, scooter, operate machines or undertake skilled tasks 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:

- NHS – attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/
- Choice and medication: Prescribing information | Attention deficit hyperactivity disorder | CKS | NICE

12. Pregnancy, paternal exposure and breast feeding

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: https://www.medicinesinpregnancy.org/Medicine--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-by-case 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-in-lactation-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

Add name of specialist(s) responsible for patient assessment, diagnosis & prescribing recommendation.

1. Name 1 (add qualification)

2. Name 2 (add qualification)
3. Name 3 (add qualification)

Add email address:

Add any alternative contacts:

Add contact phone number:
Add contact days / hours available:

Out of hours contact details: Consider emergency services

If a patient requires additional support, which is not related to their ADHD treatment, then referral via a health, education or social care practitioner, would normally be required.

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. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References

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- 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

- 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-between-primary-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/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/

17. Local arrangements for referral

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

- Specialist contacts patient's GP requesting transfer of prescribing and monitoring responsibility as detailed within this shared care. Note: The request to prescribe must be accompanied by sufficient clinical information in order for the patient's GP to be able to consider the appropriateness of the request to prescribe in response to the details of the assessment, diagnosis and medication initiation and stabilisation. Full details can be found here Frimley ICB Policy Statements: Request to prescribe following referral to a young person's ADHD service.

- Specialist completes and signs Appendix 1 & sends to patient's GP (GP may need to forward a copy of shared care document to provider – available here Frimley ICB Shared Care Documents).

- GP completes Appendix 2 or Appendix 3 as appropriate to confirm their decision and sends to provider.
- GP either takes over prescribing responsibility & monitoring under the shared care arrangements, or if declined, the provider is responsible for ongoing prescribing and monitoring for the individual.
- When seeking specialist advice relating to the management of ADHD for an individual continuing with shared care, see section 13 for contact details.
- If the patient develops a concurrent mental health or neurodevelopmental condition requiring specialist care where their ADHD is best managed by the specialist service, reassume prescribing responsibilities, or inform the patient's GP that a referral to an alternative provider is required in order to properly support the patient's change in condition.

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 **Frimley ICB shared care protocol** for *[insert medicine name]* 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 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*
I have enclosed a copy of the shared care protocol which covers this treatment	*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	
I have arranged a follow up with this patient in the following timescale	

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.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

Specialist* signature: _____

Specialist name (PRINT): _____

Specialist qualification(s): _____
Date: _____

** A healthcare professional with training and expertise in managing ADHD. This may include a consultant, doctor, nurse or pharmacist specialising in diagnosing and managing ADHD.*

Appendix 2: 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/oraddress]*

Thank you for your request 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.

Primary Care Prescriber signature: _____

Primary Care Prescriber name (PRINT): _____

Date: _____

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (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 the interest of patient safety, NHS Frimley ICB, in conjunction with local acute trusts have classified *[insert medicine name]*as a Shared Care medication, and requires a number of conditions to be met before transfer can be made to primary care.

Shared care is a term used within the NHS to describe the situation where a specialist doctor wishes to pass some of the patient's care, such as prescription of medication, over to their general practitioner (GP). This is something that can be requested but the guidance is that this may only be done if the GP agrees. The GP will need to consider a number of factors to decide if this is safe.

If care is transferred, from this point the primary care prescriber will be responsible for the prescriptions they sign. The GMC states that when taking on prescribing, all clinicians must keep informed about the medications they prescribe. They need to be able to recognise serious and adverse side effects and ensure that appropriate clinical monitoring arrangements are in place. They must also ensure adequate monitoring. This is a significant responsibility and decisions must be made carefully bearing this in mind.

GPs need to be mindful of focussing on undertaking essential services to put patients first and foremost before agreeing to take on extra work; not working beyond their competences or over safety limits.

If a GP feels that it is not appropriate for any reason for them to take over this extra work, then appropriate arrangements for the continuing care of the patient would be as a default that the prescribing should remain with the specialist service.

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

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail.

Yours sincerely

Primary Care Prescriber signature: _____

Primary Care Prescriber name (PRINT): _____

Date: _____

Primary Care Prescriber address/practice stamp