





National shared care protocol:

Methylphenidate in adult services

1 January 2025, Version 1

TLS Amber – 3 Months

Review date - January 2028

The content of this shared care protocol was correct as of January 2022. As well as these protocols, please ensure that <u>summaries of product characteristics</u> (SPCs), <u>British</u> <u>national formulary</u> (BNF) or the <u>Medicines and Healthcare products Regulatory</u> <u>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 (<u>section 2</u>) 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 <u>section 11</u>), 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 <u>section 4</u>) and interactions (see <u>section 7</u>).
- Conduct required baseline investigations and initial monitoring (see <u>section 8</u>).
- Initiate and optimise treatment as outlined in section 5. Prescribing is normally for at least 12 weeks until the patient is stable and dose optimised.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, brand to be prescribed, current and ongoing dose, any relevant test results and any additional monitoring. Include contact information (<u>section 13</u>).
- Prescribe sufficient medication 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. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. 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. Trial discontinuations can
 be managed in primary care within the competence of the prescriber (section 8) with
 advice/input from the specialist.
- Prescribing when a woman becomes or wishes to become pregnant can be managed in primary care with advice/input from the specialist.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Respond to the request from the specialist as soon as practicable if they are **unable** to support shared care (in writing or via secure email). 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 <u>section 5</u>, taking into account any potential drug interactions in <u>section 7</u>.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Adjust the dose of methylphenidate prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in <u>section 9</u>. Communicate any abnormal results to the specialist.
- Assess for possible interactions with methylphenidate when starting new medicines (see section 7).
- Manage any adverse effects as detailed in <u>section 10</u> and discuss with specialist team when required.
- Stop methylphenidate and make an urgent referral for appropriate care when contraindications are suspected.
- Seek advice/input from the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations can be managed in primary care within the competence of the prescriber with advice/input from 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 to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in <u>section 11</u>.
- Report the use of any over the counter (OTC) medications to their 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 <u>NICE Guidance NG87 Attention deficit hyperactivity disorder: diagnosis and management</u>. 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 <u>NICE Guidance NG46 Controlled drugs: safe use and management</u>. 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

 Attention deficit hyperactivity disorder (ADHD) in adults. Some brands are not licensed in adults (see <u>section 6</u>)

3. Locally agreed off-label use

To be agreed and completed locally (include supporting information) N/A

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 $\underline{\mathsf{BNF}}$ & $\underline{\mathsf{SPC}}$ for comprehensive information.

Contraindications:

- Known 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
- 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.

For patients with the following contraindications, methylphenidate can be prescribed under certain circumstances after a risk benefit consideration by the specialist has been taken into account:

- 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 moderate hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart

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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.

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 after the patient has been on treatment for at least 12 weeks, is stable and the dose optimised 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.
- Dose or formulation adjustments can be managed in primary care with advice/input from the specialist.
- Termination of treatment can be managed in primary care within the competence of the prescriber (section 8) with advice/input from the specialist.

Initial stabilisation:

Recommended starting dose in ADHD:

- Immediate release tablets: 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. <u>Consult SPC for the prescribed brand for more information.</u>

Methylphenidate must be prescribed by the initiating specialist during initiation and dose stabilisation.

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
- <u>Modified release capsules</u>: 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 <u>BNF</u> and <u>SPC</u>.

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 and primary care prescriber of the outcome. Alternatively, this can be managed in primary care within the competence of the prescriber (<u>section 8</u>).

If there are concerns about declining renal/hepatic function, discuss and agree the need for periodic hepatic/renal monitoring on an individual patient basis with the specialist.

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

	NB: Methylphenidate standard release tablets are not licensed for use in adults. Use is considered off-label. Brand name prescribing is not necessary for standard release tablets.
	Prolonged-release tablets: NB: Modified-released preparations vary in their release characteristics and guidance from the MHRA states that methylphenidate must be prescribed according to brand. Concerta 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 Affenid XL®: 18mg, 27mg, 36mg, 54mg NB: Not all methylphenidate prolonged-release tablets are licensed for use in adults. Please consult the relevant <u>SPC</u> for brand-specific licensing information, to see if prescribing is off-label.
	Modified-release capsules: NB: Modified-released preparations vary in their release characteristics and <u>must be prescribed by brand name</u> . The specialist must specify the brand to be prescribed. Equasym XL®: 10mg, 20mg, 30mg Medikinet XL® ▼: 5mg, 10mg, 20mg, 30mg, 40mg, 50mg, 60mg Metyrol XL®: 10mg, 20mg, 30mg, 40mg, 60mg Meflynate XL®: 10mg, 20mg, 30mg, 40mg, 60mg Ritalin XL®: 10mg, 20mg, 30mg, 40mg, 60mg NB: Ritalin XL, Medikinet XL, Metyrol XL and Meflynate 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 <u>SPC</u> 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. Prolonged-release tablets must be swallowed whole with the aid of liquids, and must not be chewed, divided, or crushed. Methylphenidate capsules can be opened and sprinkled on a small amount of soft food for administration. Please consult the relevant <u>SPC</u> for brand-specific information.

	If a dose is missed then the next scheduled dose should be taken as usual; <u>a</u> <u>double dose should not be taken to make up for a missed dose</u> .			
Other important information:	Methylphenidate is a schedule 2 controlled drug and is subject to <u>legal</u> <u>prescription requirements</u> . 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. In times of medicine shortages, local guidance is available to support clinicians to manage supply disruptions. <u>Management of Stock</u> <u>Shortages (Remedy BNSSG ICB)</u>			
7. Significant medicine interactions Back to top 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				
methylpheni	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

• **Clonidine):** Serious adverse events, including sudden death, have been reported in concomitant use with clonidine

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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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 prescribing and monitoring be transferred to primary care.

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)
- Appetite
- 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
 - o Sudden death in a first-degree relative under 40 years suggesting a cardiac disease
 - Shortness of breath on exertion compared with peers
 - Fainting on exertion or in response to fright or noise
 - o Palpitations
 - Chest pain suggestive of cardiac origin
 - Signs of heart failure, heart murmur or hypertension
 - o Current treatment with a medicine that may increase cardiac risk

Initial monitoring:

- After every change of dose: assess heart rate, blood pressure, changes in weight, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring.
- Assessment of symptom improvement. Discontinue if no improvement is observed after reaching normal therapeutic doses.

Ongoing monitoring (ADHD):

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on 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.

In BNSSG the annual review is done in primary care for patients registered at GP practices signed up to the ADHD locally enhanced service (LES) and by the specialist team where the GP practice is not signed up to the LES.

Patients should be encouraged to consider stopping the medication every 1 to 5 years, with the guidance of the specialist if desired. If desired and clinically appropriate, Methylphenidate can be restarted by the GP, referral back into the ADHD service is not necessary.

9. Ongoing monitoring requirements to be undertaken by primary care

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

Monitoring	Frequency
 Blood pressure and heart rate Weight and appetite Assessment for new or worsening psychiatric signs or symptoms (e.g. anxiety, symptoms of bipolar disorder). Ask patients "Do you believe your mental wellbeing has suffered due to your ADHD medications?" Explore whether patient is experiencing any difficulties with sleep 	Every 6 months, and after any change of dose recommended by specialist team.
 Assessment of adherence, and for any indication of methylphenidate abuse, misuse, or diversion 	As required, based on the patient's needs and individual circumstances.
 Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD 	Annually

(If relevant) 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 Back to top 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 Scheme Section S				
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 Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP Weight or BMI outside healthy range, anorexia or weight loss	 In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management In absence of recent dose changes, reduce dose by half and discuss with specialist or cardiology for further advice. Exclude other reasons for weight loss. Give advice as per <u>NICE NG87</u>: 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 NB: no haematological monitoring is recommended. Haematological disorders would be a chance finding/due to patient reporting adverse drug reactions.	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 neurological assessment
New or worsening seizures	Discontinue methylphenidate. Discuss with 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. Discuss with specialist if difficulty persists; dose reduction may be required.
Suspicion of abuse, misuse, or diversion	Discuss with specialist

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.

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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 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, or medicines affect their ability to drive safely. See <u>https://www.gov.uk/adhd-and-driving</u> or <u>https://www.gov.uk/narcolepsy-and-driving</u>.
- 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 <u>https://www.gov.uk/guidance/controlled-drugs-personal-licences</u>.

Patient information:

- Royal College of Psychiatrists ADHD in adults. <u>https://www.rcpsych.ac.uk/mental-health/problems-disorders/adhd-in-adults</u>
- NHS Attention deficit hyperactivity disorder. <u>https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/</u>

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 and/or the pregnant woman.

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. Ongoing prescribing in pregnancy may be managed in primary care within the competence of the prescriber with advice/input from the specialist.

Healthcare professional information available from:

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

Patient information available from: <u>https://www.medicinesinpregnancy.org/Medicine--</u> 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: <u>Breastfeeding Medicines Advice service –</u> <u>SPS - Specialist Pharmacy Service – The first stop for professional medicines advice</u>

Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified. Further information for patients: <u>bumps - best use of medicine in pregnancy</u> (medicinesinpregnancy.org)

13. Specialist contact information

Name: Dr Dietmar Hank

Role and specialty: Consultant Psychiatrist and Clinical Lead Adult ADHD service, AWP Daytime telephone number: 01275 796262 M-F 9-5 Email address: *Awp.specialisedadhdservices@nhs.net* Alternative contact: Out of hours contact details:

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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- Specialist Pharmacy Service. Medicines Q&A: Which medicines should be considered for brand-name prescribing in primary care? <u>Prescribing by generic or brand name in primary</u> <u>care – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice</u> on 15/01/2025
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- NICE. NG46: Controlled drugs: safe use and management. April 2016. Accessed via <u>https://www.nice.org.uk/guidance/ng46/</u> on 15/01/2025
- 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: <u>10.1177/0269881113519509</u>
- UKTIS. Use of methylphenidate in pregnancy. <u>https://www.toxbase.org/poisons-index-a-z/m-products/methylphenidate-in-pregnancy/</u> [requires registration to access]

16. Other relevant national guidance

- NHSE guidance Responsibility for prescribing between primary & secondary/tertiary care. Available from <u>https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/</u>
- 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/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. <u>https://www.nice.org.uk/guidance/ng197/</u>.

17. Local arrangements for referral

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

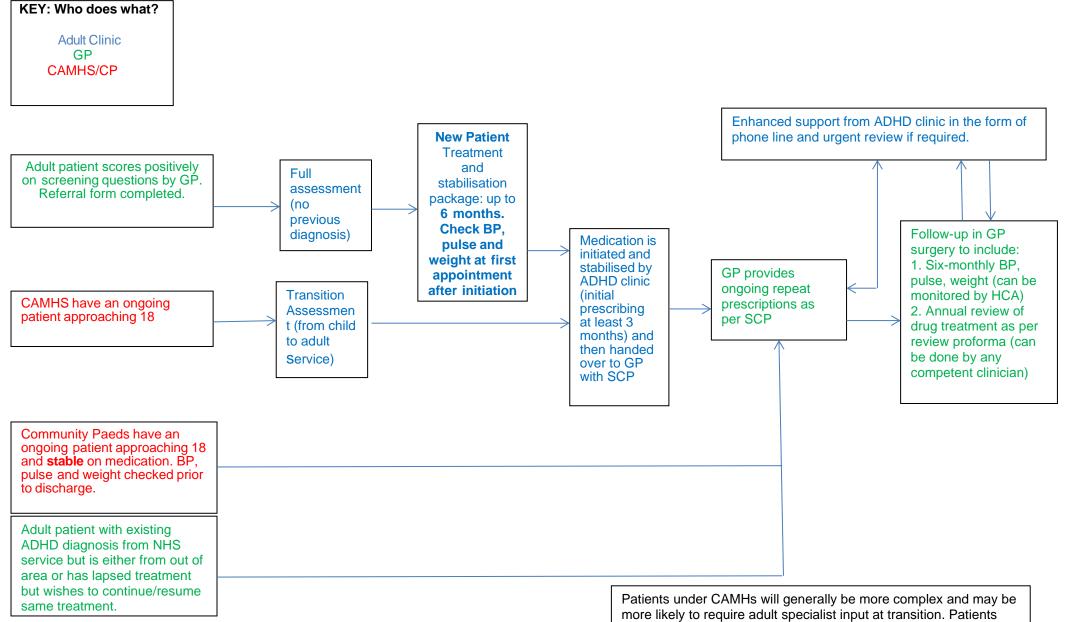
Contact specialist for advice if:

- The patient finds the medication intolerable for any given reason
- If there is concern about observed mental or physical side effects (e.g. depression or hypertension)
- The side effects mentioned above, do not appear to be of a temporary and short lived nature.

Contact named responsible clinician in writing or via secure email detailed in clinic letter. See flow diagram below for referral pathways for GP practices signed up to the ADHD LES.

Approved by BNSSG JFG: January 2025 Review date: September 2027 Version 1

BNSSG Adult ADHD referral and treatment pathway – GP Practices signed up to ADHD LES



18 National shared care protocol: Methylphenidate in adult services

Patients under CAMHs will generally be more complex and may be more likely to require adult specialist input at transition. Patients under Community Paediatrics will generally be defined as more stable and able to be moved to care of the GP at transition.