NHS Dorset

SHARED CARE PROTOCOL - METHYLPHENIDATE FOR ADULTS AND CHILDREN WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD). INCLUDES USE IN NARCOLEPSY BUT ONLY IN ADULTS

As well this protocol, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE 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.
- Provide a review:
  - to confirm the patient meets the criteria for ADHD and needs treatment
  - of the patient's mental health and social circumstances, including:
    - presence of coexisting mental health and neurodevelopmental conditions
    - current educational or employment circumstances
    - risk assessment for substance misuse and drug diversion
    - care needs
- 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 them to reach an informed decision. Obtain and document consent. Provide an appropriate patient information leaflet.
- Explain where drugs are used outside of their license
- 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 scheduled reviews, baseline investigations and monitoring (see section 8) and communicate the results to primary care.

- Initiate, assess response and optimise treatment as outlined in section 5. Transfer to primary care is normally after the patient has been treated for 3 months and with satisfactory investigation results for at least 4 weeks.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Explain the intention to share care for drug prescribing and monitoring to the patient and/or their carer. Explain the process and the potential timescales for this.
- Once treatment is optimised, request shared care from the primary care provider either using the documentation in Appendix 1 or by clinic letter, 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 taking into account any delays in communication to general practice to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- 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 should be managed by the specialist.
- Ensure there is a mechanism to receive rapid referral of a patient from primary care in the event of deteriorating clinical condition, non-adherence to monitoring requirements or need for further advice and support
- Provide advice to the patient and/or primary care prescriber if a patient becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.
- Advise primary care if treatment should be discontinued

Primary care responsibilities

- To refer the patient for specialist advice using the ADHD referral pathway if not already known by a Dorset ADHD specialist team. Initial referral should include:
  - For Adults:
    - ❖ Adult Self-Report Scale Checklist (ASRS) to be completed by the patient prior to specialist assessment
    - ❖ Physical assessment (In accordance with the recommendations from NICE NG87) including:
      - Medical history
      - Medication history
      - Height and weight (measured and recorded against the normal range for age, height and sex)
      - Baseline pulse and blood pressure (measured with an appropriately sized cuff and compared with the normal range for age)
    - ❖ Cardiovascular assessment- Consider whether further physical testing/monitoring (such as blood tests, ECG, etc) or a cardiologist opinion is required.
    - ❖ Drugs and alcohol screen
    - ❖ Psychiatric history
    - ❖ Previous treatment
  - For Children and Adolescents: patients should be referred to either CAMHS or paediatric services.
- Respond to the request from the specialist for shared care if further clarification or a refusal is intended. Acceptance of shared care is implied by nil response. It is asked that this be undertaken within 14 days of the request being received, where possible.
- If shared care is accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5 taking into account any potential drug interactions in section 7.
- 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 section 9. Communicate any abnormal results to the specialist.
- Assess for possible interactions with methylphenidate when starting new medicines (see section 7)
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop methylphenidate and make an urgent referral for appropriate care if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected.

- Refer the patient back to the specialist if the patient becomes or plans to become pregnant or if the clinical condition worsens or there is non-adherence to monitoring requirements
- Consider referring back to the specialist if withdrawal of treatment might be indicated. This could be because the patient is well controlled and has been free of ADHD symptoms for at least one year whilst taking medication; ADHD symptoms are not evident on days when medication is forgotten or missed or there has been no need to increase the dose of medication in child or adolescent patients despite growth and weight gain over the preceding one to two years
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.

Patient and/or carer responsibilities

- Take methylphenidate as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Maintain engagement with specialist and primary care; attending regularly for monitoring and review appointments as requested; keeping their contact details up to date with both teams. Be aware that medicines may be stopped if they do not attend for the blood monitoring or review 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 (OTC) to their primary care prescriber and be aware they should discuss the use of methylphenidate with their pharmacist before purchasing any OTC medicines.
- Tell anyone who prescribes them a medicine that they are taking methylphenidate.
- 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 and/or carers 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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This shared care guideline has been prepared to support the transfer of responsibility for prescribing from secondary to primary care. Shared Care is only appropriate if it provides the optimum solution for the patient.

Methylphenidate is a central nervous system stimulant licensed as part of a comprehensive treatment programme for ADHD. It may be offered as a first line pharmacological treatment option for adults with ADHD who have been appropriately diagnosed (see NICE guidance for ADHD NG87). 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. Please refer to the Dorset Formulary local guidance regarding stock/ product availability or shortages.

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) or by a Paediatric Service and approaching their 18th birthday, it is expected that CAMHS or the Paediatric Service will refer to the appropriate adult service if a need for ongoing treatment is anticipated. NICE Guidance NG43 Overview | Transition from children's to adults' services for young people using health or social care services | Guidance | NICE NG43 should be followed.

The NICE guidance for ADHD makes a recommendation for treatment in children 5 years and over. Medicines for treating ADHD do not have a UK marketing authorisation for use in children under the age of 6 years so the use as per the NICE recommendation is off label. For children under 5 years old, an ADHD-focused group parent-training programme should be offered to parents or carers of children under 5 years with ADHD as first-line treatment. If this fails, the advice of a specialist ADHD service with expertise in managing ADHD in young children (ideally a tertiary service) should be sought.

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 by a healthcare professional with expertise in ADHD, 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).
- Narcolepsy in adults (Off-label indication).

Please note licensed indications vary by manufacturer; see SPC for full details. Some brands are not licensed in adults (see section 6)

3. Locally agreed off-label use

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Nil additional identified- see above

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.
- 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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- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- Additional caution (smaller initial dosing) should be considered where there are other neurodevelopmental comorbidities
- 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.

Recommended starting dose in ADHD

ADHD Initial Stabilisation

Additional caution (smaller initial dosing) should be considered where there are other neurodevelopmental comorbidities

Immediate release tablets

Child 4–5 years (note NICE recommendations from 5 years of age)

Initially 2.5 mg twice daily, increased in steps of 2.5 mg daily if required, at weekly intervals according to response

Child 6–17 years

Initially 5 mg 1–2 times a day, increased in steps of 5–10 mg daily if required, at weekly intervals according to response

Adults

Initially 5 mg 2–3 times a day, dose is increased, if necessary, at weekly intervals according to response

Modified release tablets

Child 6–17 years

Initially 18 mg once daily, dose to be taken in the morning increased, if necessary, at weekly intervals according to response

Adults

Initially 18 mg once daily, dose to be taken in the morning increased, if necessary, at weekly intervals according to response

Modified release capsules

Child 6–17 years

Initially 10 mg once daily, dose to be taken in the morning before breakfast; increased gradually at weekly intervals if necessary

Adult

Initially 10 mg once daily, dose to be taken in the morning before breakfast; increased gradually at weekly intervals if necessary.

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

ADHD Maintenance dose (following initial stabilisation):

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

ADHD Maximum dose:

Immediate release tablets

Child 4–5 years (note NICE recommendations from 5years of age)

Dose increased if necessary up to 1.4 mg/kg daily in 2–3 divided doses, discontinue if no response after 1 month, if effect wears off in evening (with rebound hyperactivity) a dose at bedtime may be appropriate (establish need with trial bedtime dose).

Child 6–17 years

Dose increased if necessary up to 60 mg daily in 2–3 divided doses, increased if necessary up to 2.1 mg/kg daily in 2–3 divided doses. The licensed maximum dose is 60 mg daily in 2–3 doses, higher dose (up to a maximum of 90 mg daily) under the direction of a specialist, discontinue if no response after 1 month, if effect wears off in evening (with rebound hyperactivity) a dose at bedtime may be appropriate (establish need with trial bedtime dose).

Adults

Dose increased if necessary up to 100 mg daily in 2–3 divided doses, if effect wears off in evening (with rebound hyperactivity) a dose at bedtime may be appropriate (establish need with trial bedtime dose).

Modified release tablets

Child 6–17 years

Dose increased in steps of 18 mg every week, adjusted according to response; licensed max. dose is 54 mg once daily. Use of higher doses only under direction of specialist; discontinue if no response after 1 month; maximum 108 mg per day.

Adults
Dose adjusted in steps of 18mg at weekly intervals according to response; maximum 108 mg per day.

Modified release capsules
Child 6–17 years
Dose increased if necessary up to 2.1 mg/kg daily, licensed max. dose is 60 mg daily. To be increased to higher dose only under direction of specialist; discontinue if no response after 1 month; maximum 90 mg per day.
Adult
Dose increased gradually at weekly intervals if necessary; maximum 100 mg per day. May be given as a single dose in the morning or in divided doses in the morning and at midday, depending on brand.

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

Patients started on immediate release tablets may switch to extended-release preparations if once daily dosing is preferable. MHRA advises caution if switching between long-acting products due to differences in formulations Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to differences in formulations - GOV.UK

Adults with ADHD who have shown clear benefit from methylphenidate in childhood or adolescence may continue treatment into adulthood at the same daily dose. The use in adults is off label with some brands and the maximum licensed daily dose varies with formulation and brand; consult BNF and SPC.

Narcolepsy in adults
Recommended starting dose in narcolepsy (off-label):
- Immediate release tablets: 10 mg daily in divided doses, to be taken before meals

Usual dose in narcolepsy (off-label):
- Immediate release tablets: 20-30 mg daily in divided doses, taken before meals. Maximum dose 60 mg daily

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

Conditions requiring dose adjustment:

The last dose of immediate release tablets should, in general, not be given within 4 hours before bedtime in order to prevent disturbances in falling asleep. However, if the effect of the drug wears off too early in the evening, disturbed behaviour and/or inability to go to sleep may recur. A small evening dose may help to solve this problem. The pros and cons of a small evening dose versus disturbances in falling asleep should be considered.

In patients taking modified release tablets an additional immediate release methylphenidate tablet in the late afternoon may help if the duration of action is too short

In patients taking modified release capsules they may require twice daily dosing or the addition of an immediate release tablet if duration of action is too short

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- it is recommended that this happens at least once yearly. This preferably should happen during the school holidays where 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

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Route of administration:	Oral
Formulation:	**Please refer to the Dorset Formulary local guidance regarding stock/ product availability or shortages** 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.

	<u>Prolonged-release tablets</u>: 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. Affenid XL ®: 18mg, 27mg, 36mg, 54mg 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 **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 adults. Use in this way is considered off-label.** **<u>Modified-release capsules</u>:** 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 Meflynate XL®: 10mg, 20mg, 30mg, 40mg, 60mg Metyrol XL®: 10mg, 20mg, 30mg, 40mg, 60mg Ritalin XL®: 10mg, 20mg, 30mg, 40mg, 60mg **NB: Ritalin XL, Medikinet XL, Meflynate XL and Metyrol 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. There is an exception with Medikinet XL. The manufacturer advises that Medikinet XL has to be taken with or after a meal in order to obtain sufficiently prolonged action and to avoid high plasma peaks. Methylphenidate hydrochloride is absorbed much faster from Medikinet XL when the medicinal product is taken on an empty stomach. In this case, release may not be adequately sustained. Therefore Medikinet XL should not be administered without food.

	Prolonged-release tablets should only be used in patients who are able to swallow the tablet whole with the aid of liquids if needed. Tablets should not be chewed, divided, or crushed. The medication may be contained within a nonabsorbable shell designed to release the drug at a controlled rate. The tablet shell is eliminated from the body and patients should be counselled and reassured on the possibility that they may occasionally notice in their stool something that looks like a tablet. Prolonged release tablets can be nondeformable and do not appreciably change in shape in the gastrointestinal (GI) tract. They should not ordinarily be administered to patients with pre-existing severe GI narrowing (pathologic or iatrogenic) or in patients with dysphagia or significant difficulty in swallowing tablets. Modified release capsules can be swallowed whole with the aid of liquids, or alternatively the capsule may be carefully opened and the capsule contents sprinkled over soft food e.g. apple sauce or yoghurt. The food should not be warm because this could affect the prolonged-release properties of the formulation. The mixture of drug and food should be consumed immediately in its entirety. The drug and food mixture should not be stored for future use. Drinking some fluids, e.g. water, should follow the intake of the sprinkles with soft food. The capsules and the capsule contents must not be crushed or chewed. 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

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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 full assessment, as recommended by NICE guidance for ADHD. This should include a medical history and cardiovascular assessment, taking into account conditions that may present 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
  - 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
  - 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 and blood pressure, 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 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 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

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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/pulse and assessment for cardiovascular signs or symptoms • Weight, height and appetite • Assessment for new or worsening psychiatric and neurological signs or	Every 6 months, and after any change of dose recommended by specialist team. NB: In children under 10 years measure weight every 3 months

symptoms (e.g. tics, anxiety, symptoms of bipolar disorder) • Explore whether patient is experiencing any difficulties with sleep	
• 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

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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 Tachycardia (resting HR greater than 120bpm), arrhythmia, palpitations, clinically significant increase in systolic BP	• 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.
Abdominal Pain, diarrhoea, nausea and vomiting, dry mouth, dyspepsia	• Occurs at initiation. May be alleviated by concomitant food intake. • Refer to specialist for advice if continues

Decreased appetite; weight or BMI outside healthy range including 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 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	Stop treatment and discuss with specialist. Consider referral for urgent psychiatric assessment if suicide related behaviour, mania or psychosis are present. Discuss ongoing benefit of treatment with specialist team.
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	If exacerbated in a young person with epilepsy or de novo seizures emerge, discontinue the drug immediately. 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/ other sleep disturbance or nervousness	Review dose and/or omit afternoon/evening dose if using TDS immediate release tablet regime – refer to specialist for advice. Give advice on sleep hygiene.
Suspicion of abuse, misuse, or diversion	Discuss with specialist team

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 and/or carer 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. If an erection persists for more than 2 hours go to A&E; this is an emergency.
- 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
- Report suicidal thoughts or behaviour, and development or worsening of irritability, agitation, and depression.
- New or worsening neurological symptoms (e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory)

- Development of symptoms such as exertional chest pain, unexplained syncope, or other symptoms
  suggestive of cardiac disease during treatment
- 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 and/or carer 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.
- Height and weight should be recorded as advised with maintenance of a growth chart as appropriate
- Keeping a sleep diary may help identify any changes in sleep patterns
- Not to drive or operate machines if methylphenidate affects their ability to do so safely, e.g. by causing dizziness, drowsiness, fatigue or visual disturbances. Dexamfetamine can affect impair cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving. For information on 2015 legislation regarding driving whilst taking certain controlled drugs, including amfetamines, see drugs and driving: the law.
- 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 and/or carers 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/problems-disorders/adhd-in-adults
- Royal College of Psychiatrists ADHD and hyperkinetic disorder for parents
- NHS – attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/
- Patient leaflet for children: https://www.medicinesforchildren.org.uk/medicines/methylphenidate-for-adhd/
- Narcolepsy UK – methylphenidate. https://www.narcolepsy.org.uk/resources/methylphenidate
- 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.

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.

Paternal exposure:
No evidence regarding adverse outcomes following paternal exposure was identified.

13. Specialist contact information

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Please approach the patient's named secondary care clinician via the usual method of communication, mainly currently email or letter. Phone numbers and email available on clinic letters

14. Additional information

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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 of any changes to the patient's GP or their contact details. All involved healthcare professionals should ensure a prompt transfer of care that includes effective information sharing and continued access to the medicines by the patient during the transition.

15. References

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- eBNF. Methylphenidate. Methylphenidate hydrochloride | Drugs | BNF | NICE
- EBNF (Children's) Methylphenidate Methylphenidate hydrochloride | Drugs | BNFC | NICE
- Affenid XL 18 mg prolonged release tablets - Summary of Product Characteristics (SmPC) - (emc)
- Concerta XL 18 mg prolonged-release tablets - Summary of Product Characteristics (SmPC) - (emc)
- Delmosart Tablets | Accord-UK Products; UK-delmosart-SmPC-18mg-prolonged-releasetablets-V11.0-20230707 (PL 0142/1220)
- Equasym XL 10 mg Capsules - Summary of Product Characteristics (SmPC) - (emc)
- Matoride XL 18 mg Prolonged-release Tablets - Summary of Product Characteristics (SmPC) - (emc)
- Medikinet 10 mg tablets - Summary of Product Characteristics (SmPC) - (emc)
- Medikinet XL 5 mg modified-release capsules, hard - Summary of Product Characteristics (SmPC) - (emc)
- Meflynate XL 10 mg modified-release hard capsules - Summary of Product Characteristics (SmPC) - (emc)
- Methylphenidate Hydrochloride 10 mg Tablets - Summary of Product Characteristics (SmPC) - (emc)

- Metyrol XL 10 mg modified-release hard capsules - Summary of Product Characteristics (SmPC) - (emc)
- Ritalin 10mg Tablets - Summary of Product Characteristics (SmPC) - (emc)
- Ritalin XL 10 mg modified-release hard capsules - Summary of Product Characteristics (SmPC) - (emc)
- Xaggitin XL 18mg Prolonged-release Tablets - Summary of Product Characteristics (SmPC) - (emc)
- Xenidate XL 18 mg Prolonged-release Tablets - Summary of Product Characteristics (SmPC) - (emc)
- NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via https://www.nice.org.uk/guidance/ng87/ on 14/04/21
- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: Methylphenidate. Last revised January 2021. Accessed via https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/methylphenidate/ on 04/05/2021
- Specialist Pharmacy Service. Medicines Q&A: Which medicines should be considered for brand-name prescribing in primary care? Prescribing by generic or brand name in primary care – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice on 05/05/2021
- Home Office. Guidance: List of most commonly encountered drugs currently controlled under the misuse of drugs legislation. Updated December 2019. Accessed via https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation on 05/05/2021
- NICE. NG46: Controlled drugs: safe use and management. April 2016. Accessed via https://www.nice.org.uk/guidance/ng46/ on 05/05/2021
- 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

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-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

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

Via the usual methods

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 *[insert APC name]*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/the SCP can be found here (insert electronic/ web link)	*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.

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist). Not routinely used in the Dorset system, acceptance of shared care is implied by a nil return.

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

Medicine	Route	Dose & frequency

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

Primary Care Prescriber signature: _____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 *[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:

		Tick which apply
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** As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **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** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **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** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***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** As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***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** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed***.*** For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***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)**	

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 information to individual GPs." In this case we would also see the term GP being interchangeable with the 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

Yours sincerely

Primary Care Prescriber signature: _____Date: _____

Primary Care Prescriber address/practice stamp