NHS Dorset

SHARED CARE PROTOCOL – DEXAMFETAMINE 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 specialist's request and as per section 5 considering any potential drug interactions in section 7.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Adjust the dose of dexamfetamine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Assess for interactions with dexamfetamine when starting new medicines (see section 7)
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop dexamfetamine 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 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 dexamfetamine as prescribed and avoid abrupt withdrawal unless advised by 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 to their primary care prescriber and be aware they should discuss the use of dexamfetamine with their pharmacist before purchasing any OTC medicines.
- Tell anyone who prescribes them a medicine that they are taking dexamfetamine.
- Be aware that dexamfetamine can affect cognitive function and is subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving (see section 11).
- Avoid alcohol while during treatment, as it may make some side effects worse. Avoid recreational drugs.
- Dexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions and should store dexamfetamine 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.

Dexamfetamine sulfate is a sympathomimetic amine with central stimulant and anorectic activity indicated for the treatment of attention deficit hyperactivity disorder (ADHD). It may be offered as an alternative treatment in patients who have been appropriately diagnosed and whose symptoms are responding to lisdexamfetamine but are unable to tolerate the drug's longer effect profile (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.

Dexamfetamine 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.

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.

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

Long-term usefulness of dexamfetamine for extended periods (over 12 months) should be periodically re-evaluated by a healthcare professional with expertise in ADHD for the individual patient with trial periods off medication to assess the patient's functioning without pharmacotherapy. It is recommended a trial discontinuation at least once yearly to assess the

patient's condition. Improvement may be sustained when the medicinal product is either temporarily or permanently discontinued.

Dexamfetamine is not licensed for use in adults for refractory attention deficit hyperactivity disorder. 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 with or without cataplexy

(Please note licensed indications vary by manufacturer. See SPCs for full details).

3. Locally agreed off-label use

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Nil 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:

- Known hypersensitivity to the active substance, any of the excipients, or sympathomimetic amines
- Glaucoma
- Phaeochromocytoma
- Certain pre-existing cardiovascular disorders constitute contraindications unless specialist cardiac advice is obtained and documented. These include structural cardiac abnormalities and/or moderate or severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (disorders caused by the dysfunction of ion channels)
- Advanced arteriosclerosis
- Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of MAOI treatment

- Hyperthyroidism or thyrotoxicosis.
- Severe depression, anorexia nervosa/anorexic disorders, suicidal ideation, hyperexcitability, psychotic symptoms, severe and episodic (Type I) Bipolar (affective) Disorder (that is not well-controlled), schizophrenia, psychopathic/borderline personality disorder
- Gilles de la Tourette syndrome or similar dystonia
- Cerebrovascular disorders (cerebral aneurysm, vascular abnormalities including vasculitis or stroke)
- Porphyria
- History of drug abuse or alcohol abuse
- Pregnancy (see section 12)

Cautions:

- History of epilepsy (discontinue if seizures occur)
- Mild hypertension, history of cardiovascular disease, or concomitant medications that elevate blood pressure
- susceptibility to angle-closure glaucoma
- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour, tics, anxiety/agitation, or bipolar disorder
- Depressive symptoms: patients should be screened for risk of bipolar disorder, including psychiatric and family histories.
- Renal and hepatic insufficiency (due to lack of data).
- Family history of sudden cardiac or unexplained death or malignant arrhythmia
- 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.

ADHD Initial stabilisation:

Adults ADHD: Initially 5mg twice daily, increasing after 1-2 weeks to three times daily if extended duration of action is required, then in 5mg dosage increments as necessary depending on treatment response and side-effects.

Children 6-17 years: ADHD: Initially 2.5 mg 2–3 times a day, increased in steps of 5 mg once weekly if required. Normally the first increasing dose is given in the morning.

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

ADHD Maintenance dose (following initial stabilisation):

Adults ADHD: dose should be increased according to response at intervals no shorter than 1 week. Maximum 60 mg per day to be given in 2–4 divided doses

Children 6-17 years: ADHD: usual maximum 1 mg/kg daily, up to 20 mg daily (40 mg daily has been required in some children); maintenance dose to be given in 2–4 divided doses.

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

Narcolepsy (Adults Only)

Initial Dose: 10 mg daily in divided doses, increased in steps of up to 10 mg weekly reduced in the elderly to an initial dose of 5 mg daily in divided doses, increased in steps of 5 mg every week

Maintenance Dose: dose to be given in 2–4 divided doses; maximum 60 mg per day.

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.

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	Dexamfetamine sulfate 5mg, 10mg and 20mg immediate release tablets (Amfexa®) Dexamfetamine sulfate 5mg immediate release tablets Dexamfetamine sulfate 5mg/5mL sugar-free oral solution▼ Please note licensed indications vary by manufacturer. See SPCs for full details
Administration details:	Tablets can be halved Dexamfetamine should not be taken too late after lunch time to avoid disturbances of sleep 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:	Dexamfetamine is a schedule 2 controlled drug and is subject to legal prescription requirements. It has the potential for misuse and diversion. Patients should be advised to avoid alcohol which may exacerbate the central nervous system (CNS) side-effects of dexamfetamine. Dexamfetamine is subject to additional monitoring by the Medicines and Healthcare products Regulatory Agency (MHRA) and healthcare professionals are encouraged to report any suspected adverse reactions Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amfetamines may interfere with urinary steroid determinations

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.

The following medicines must not be prescribed without consultation with the specialist:

- **Mono-amine oxidase inhibitors (MAOIs) and other sympathomimetics** (e.g. rasagiline, selegiline, safinamide) – additive hypertensive effect
- **Clonidine** – increased duration of action of dexamfetamine, reduced antihypertensive action of clonidine

Other clinically significant interactions

- **Coumarin anticoagulants, anticonvulsants, selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants (TCAs)**: metabolism may be inhibited by dexamfetamine. Dose adjustment may be required when starting or stopping dexamfetamine.
- **SSRIs (e.g. fluoxetine, paroxetine)**: may increase exposure to dexamfetamine. Risk of serotonin syndrome.
- **Serotonergic drugs, bupropion, tapentadol, tramadol:** Risk of serotonin syndrome
- **TCAs and nabilone**: may increase risk of cardiovascular adverse events.
- **Anticonvulsants (e.g. phenobarbital, phenytoin, primidone)**: Metabolism may be inhibited, and absorption may be delayed by dexamfetamine. Dose adjustment may be required when stopping or starting dexamfetamine.
- **Antacids** (e.g. sodium bicarbonate) **and urinary alkalinizing agents** (e.g. acetazolamide, some thiazides): may increase exposure to dexamfetamine
- **Gastrointestinal acidifying agents** (e.g. ascorbic acid, fruit juices) and **urinary acidifying agents** (e.g. ammonium chloride, sodium acid phosphate): may reduce exposure to dexamfetamine
- **Antihistamines:** sedative effect may be counteracted
- **Antihypertensives, including guanethidine**: effects may be reduced by dexamfetamine
- **Beta-blockers (e.g. propranolol)**: risk of severe hypertonia. May reduce effects of dexamfetamine
- **Lithium, phenothiazines, haloperidol**: may reduce the effects of dexamfetamine
- **Disulfiram**: may inhibit metabolism and excretion of dexamfetamine

- **Opioids**: analgesic effects may be increased, and the depressant effects (e.g. respiratory depression) may be decreased by dexamfetamine
- **Halogenated anaesthetics:** risk of sudden blood pressure increase during surgery. Avoid dexamfetamine on the day of planned surgery.
- **Cytochrome P450 (CYP450) substrates, inducers, or inhibitors**: use with caution; role of CYP450 in dexamfetamine metabolism is not known
- **Alcohol:** may exacerbate adverse CNS effects of dexamfetamine
- **Apraclonidine:** effects decreased by dexamfetamine
- **Ritonavir, tipranavir:** may increase exposure to dexamfetamine

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, considering 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
- 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 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.

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 symptoms (e.g. tics, anxiety, symptoms of bipolar disorder) • Explore whether patient is experiencing any difficulties with sleep	Every 6 months, and after any change of dose recommended by specialist team. NB: In children under 10 years measure weight every 3 months

• Assessment of adherence, and for any indication of dexamfetamine 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.
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.

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.
Insomnia, sleep disturbance/nightmares, sedation, sexual dysfunction	Review timing of doses and continue treatment unless severe, Give advice on sleep hygiene. Discuss with specialist if required
Nausea, diarrhoea, abdominal cramps, constipation, dry mouth, headache, dizziness, enuresis, increased daytime urination, tics	Continue treatment unless severe. Some symptoms may be alleviated by concomitant food intake. Discuss with specialist if required
New or worsening psychiatric or neuropsychiatric symptoms, e.g. mania, depression, paranoia, anxiety, and agitation. NB: psychosis may occur following consumption of very high doses.	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
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue dexamfetamine as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary. Discuss with specialist team to determine whether dexamfetamine can be re-started.
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 regarding 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/carer should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Any mood changes, such as depression, paranoia, anxiety or agitation, psychosis, mania, and suicidal ideation
- Palpitations, chest pain or syncope
- Cerebrovascular symptoms, such as 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/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.
- 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 dexamfetamine, as it may make some side effects worse. Avoid recreational drugs.

- Due to the risks of severe depression, over-activity, extreme fatigue as well as changes in the EEG during sleep, abrupt withdrawal after a prolonged period of intake of high doses of dexamfetamine should be avoided. Patients wishing to reduce their dose or stop dexamfetamine treatment should discuss with their specialist before doing so.
- Dexamfetamine is a schedule 2 controlled drug. Patients and/or carers may be required to prove their identity when collecting prescriptions and should store dexamfetamine 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/
- Narcolepsy UK – dexamfetamine. https://www.narcolepsy.org.uk/resources/dexamfetamine
- 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:

Dexamfetamine is not recommended for use during pregnancy The limited data available shows a risk of premature birth and reduced birth weight. Infants may also develop withdrawal symptoms such as dysphoria, hyperexcitability and pronounced exhaustion.

If a patient becomes pregnant or is planning a pregnancy during treatment they should discuss treatment options with their specialist. Dexamfetamine should only be used during pregnancy if the potential benefit outweighs the risks.

Healthcare professional information available from: https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-AMFETAMINES-IN-PREGNANCY/

Breastfeeding:

Dexamfetamine is excreted in human milk, therefore a risk to infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from dexamfetamine, considering the benefit of breast feeding for the child and the benefit of therapy for the woman. High doses may interfere with lactation, although this is not confirmed in practice. If breastfeeding does take place, 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.

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.

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 the GP is responsible for letting the specialist team know if they are unhappy with continuing the shared care. 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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- Dexamfetamine sulfate | Drugs | BNF | NICE
- Dexamfetamine sulfate | Drugs | BNFC | NICE

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- 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
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- Gov.uk. Drugs and driving: the law. Accessed via https://www.gov.uk/drug-driving-law on 11/05/21.

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]* 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 regarding this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period:	
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 agree, 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 applies
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 patient's 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 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 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 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