Shared Care Agreement: Dexamfetamine for patients within adult services

This Shared Care Protocol sets out details for the sharing of care for patients prescribed Dexamfetamine for patients within adult services. This protocol is for use within the indications listed on page 5.

It should be read in conjunction with the latest Summary of Product Characteristics (SPC) available at www.medicines.org.uk/emc/.

As outlined in NHS England Guidance 2018 "Responsibility for Prescribing between Primary & Secondary/Tertiary Care. When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP concerned (and the patient) to share their care.

This document provides information on drug treatment for the shared commitment between the consultant and GP concerned. GPs are invited to participate. If the GP is not confident to undertake these roles, then they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

N.B. If the GP decides not to participate in shared care for a particular patient, they must inform the relevant specialist in writing, within 10 working days of receipt of a request to share care unless exceptional circumstances apply.

Introduction

This shared care guideline sets out details to support the transfer of responsibility for prescribing Dexamfetamine for any of the indications listed on page 5, from specialist to primary care. For further information please click on the links below:
British National Formulary and http://www.medicines.org.uk/emc/.

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Cambridgeshire & Peterborough Integrated Care System

NHS Cambridgeshire & Peterborough

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The content of this shared care protocol was correct as of May 2025. As well these protocols, 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

For ADHD:

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Ensure the patient and/or their carer understands that treatment may be stopped if they do not attend for monitoring and treatment review
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Prescribe in line with controlled drug prescription requirements (section 6).
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13). Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in section 8 and communicate the results to primary care. This monitoring, and other responsibilities below, may be carried out by a healthcare professional in primary or secondary care with expertise and training in ADHD, depending on local arrangements.
- Determine the duration of treatment and frequency of review. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate. Trial discontinuations should be managed by the specialist.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

For Narcolepsy:

The patient will be assessed by a consultant in the tertiary referral centre. If the patient agrees with the treatment plan, then the hospital will undertake to:

- Send a letter to the primary care clinician requesting shared care for the patient including details of baseline monitoring taken.
- Evaluate patients for a history of drug abuse and account for any additional risks in these patients.
- Provide information to the patient regarding the medicine.
- Provide an initial one-month supply of dexamfetamine tablets.
- Recommend an initial dose and how this may be titrated according to the response to treatment.
- Inform the primary care clinician after each clinic attendance if there is any change to treatment or monitoring.
- Inform primary care clinician of patients who do not attend clinic appointments and discuss patient's on-going treatment plan.
- Review the patient's progress on treatment. If the patient has failed to respond adequately to treatment after a reasonable period, then dexamfetamine therapy will be discontinued and other treatment options considered.
- Be available for advice to the primary care clinician.
- Answer patient/carer enquiries on any aspect of this therapy.

Primary care responsibilities

For ADHD:

- Refuse the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5 taking into account 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 possible 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 management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.

For Narcolepsy:

- Agree to shared care guideline.
- Continue to prescribe dexamfetamine once this has been initiated by the Respiratory Support and Sleep Centre (RSSC) consultant specialist.
- Report any adverse events to the hospital specialist, where appropriate.
- Request advice from the hospital specialist when necessary.
- Monitor blood pressure and pulse at each dose adjustment and at least every 6 months. The same approach to managing hypertension should be taken as for the general population (NICE Guideline 136). Please contact the Specialist via Advice and Guidance to inform them of the steps being taken to manage hypertension.
- Monitor weight and appetite at each dose adjustment and at least 6 monthly. If the patients weight drops by >10% from baseline, or they become clinically underweight (BMI<18.5) please contact specialist via the Advice and Guidance service.
- Monitor for development of de novo or worsening of pre-existing psychiatric disorders, including depression and aggressive behaviour at every dose adjustment and at least every 6 months.
- Patients should be monitored for the risk of diversion, misuse, and abuse of dexamfetamine.

Patient and/or carer responsibilities

For ADHD:

- Take dexamfetamine as prescribed and avoid abrupt withdrawal unless advised by primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in 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.
- 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.

For Narcolepsy:

- Report to the hospital specialist or primary care clinician if they do not have a clear understanding of their treatment.
- Patients must not exceed the recommended dose.
- Patients must attend their scheduled clinic and blood test appointments (where relevant).
- Must inform other clinical staff that they are receiving treatment. Report any adverse effects to the hospital specialist or primary care clinician.
- Share any concerns they have in relation to their treatment.

1. Background

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For ADHD:

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 not licensed for all the indications listed in section 2. However, its use for the indications below are established and supported by various sources and bodies including the BNF and NICE.

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.

Where a person with ADHD is treated by a Child and Adolescent Mental Health Service (CAMHS) but is approaching their 18th birthday, it is expected that CAMHS will refer to the appropriate adult service if need for ongoing treatment is anticipated.

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.

For Narcolepsy:

Narcolepsy occurs in 1 in 2500 subjects and is a chronic, debilitating, life-long neurological disease characterised by excessive daytime sleepiness with peak incidence during the second and third decades of life.

Narcolepsy may progress to include cataplexy (sudden loss of muscle tone), sleep paralysis, hypnagogic hallucinations and fragmented nocturnal sleep. Excessive, uncontrollable daytime sleepiness is experienced by all patients with narcolepsy, and is usually treated with stimulants such as dexamfetamine during the day to help keep patients awake.

Dexamfetamine Sulfate is used (licensed indication) for the treatment of narcolepsy in adult patients. At Royal Papworth Hospital, Tertiary referral centre for sleep disorders, dexamfetamine is used to manage symptoms of narcolepsy, particularly excessive daytime sleepiness. The recommendation to start treatment will be made by a specialist Consultant or their supervised delegate who will initiate dexamfetamine treatment.

Dexamfetamine should only be used in patients who have had a complete evaluation of their excessive sleepiness and in whom a diagnosis of narcolepsy has been made in accordance with diagnostic criteria. Such an evaluation usually consists of, in addition to the patient's history, sleep measurement testing in a laboratory setting and exclusion of other possible causes of the excessive sleepiness.

2. Indications

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- Attention deficit hyperactivity disorder (ADHD) in adults ‡
- Narcolepsy with or without cataplexy

‡ Off-label indications. (Please note licensed indications vary by manufacturer. See SPCs for full details).

3. Locally agreed off-label use

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As 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 dystonias.
- Cerebrovascular disorders (cerebral aneurysm, vascular abnormalities including vasculitis or stroke)
- Porphyria
- History of drug abuse or alcohol abuse.
- Pregnancy and breast-feeding (see section 12).
- Some brands of dexamfetamine sulphate tablets include lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine (there are alternative brands that do not contain lactose).
- Some brands of dexamfetamine sulphate tablets include sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine (there are alternative brands that do not contain sucrose).

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
- Potential for abuse, misuse, or diversion.

For Narcolepsy:

- To be used with caution in patients on guanethidine and patients with mild hypertension or a family history of dystonias. If tics develop, treatment with dexamfetamine should be discontinued.

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.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

Initial stabilisation:

ADHD:

- Initially 5 mg twice daily, dose should be increased according to response at intervals no shorter than 1 week.

Narcolepsy:

- Dexamfetamine is provided as 5 mg tablets.
- The initial dose is usually 5 mg twice daily, with the first dose on rising and the second dose at lunchtime.

- The dose is then typically escalated by adding 5 to 10 mg per week until symptoms are controlled or 60 mg daily in divided doses is reached.

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

Maintenance dose (following initial stabilisation):

ADHD:

- Maximum 60 mg per day to be given in 2–4 divided doses

Narcolepsy:

- Until symptom control is achieved, or 60mg daily in divided doses is reached.

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:	**ADHD Only:** Dexamfetamine sulfate 5mg, 10mg and 20mg immediate release tablets (Amfexa®▼) **ADHD and Narcolepsy:** Dexamfetamine sulfate 5mg immediate release tablets (Brown & Burk, Sovereign Medical) 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. • The effect of food on the absorption of dexamfetamine tablets has not been studied. Therefore, a possible effect of food on absorption cannot be excluded. Hence, it is recommended that dexamfetamine tablets should be taken in a standardised manner in relation to the timing of meals, i.e. that doses should be given at the same times, relative to the time of meals, on each day, preferably with or immediately after meals.
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 Special Populations: • This product contains dexamfetamine which may induce a positive laboratory test for amfetamines, particularly with an immunoassay screening test. Athletes must be aware that this medicinal product may cause a positive reaction to 'anti-doping' tests.

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:

For ADHD:

- A medical history and cardiovascular assessment, taking into account conditions that may be contraindications, risk of pregnancy (where applicable), and to ensure the patient meets the criteria for ADHD and that pharmacological treatment is required
- A risk assessment for substance misuse and drug diversion
- Blood pressure (BP) and heart rate
- Height, weight and body mass index (BMI)
- Appetite
- 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

For Narcolepsy:

- Prior to prescribing, it is necessary to conduct a baseline evaluation of the patient's cardiovascular status including blood pressure and heart rate. A comprehensive history should document concomitant medications, past and present co-morbid medical and psychiatric disorders or symptoms, family history of sudden cardiac/unexplained death and accurate recording of pre-treatment height and weight.
- Cardiovascular status:
  - Patients who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden cardiac or unexplained death or malignant arrhythmia) and physical exam to assess for the presence of cardiac disease and should receive further specialist cardiac evaluation if initial findings suggest such history or disease.

- Patients who develop symptoms such as palpitations, exceptional chest pain, unexplained syncope, dyspnoea, or other symptoms suggestive of cardiac disease during dexamfetamine treatment should undergo a prompt specialist cardiac evaluation.
- Cardiovascular status should be carefully monitored.
- Tachycardia and hypertension are potential adverse effects. Dexamfetamine should not be prescribed if the diastolic blood pressure is 100 mmHg or greater before treatment. The blood pressure should be monitored at appropriate intervals in all patients especially those with hypertension.
- Treatment with stimulants in general may lead to a minor increase in blood pressure (approximately 2 to 4 mmHg) as well as an increase in heart rate (approximately 3 to 6 beats/minute).
- In a few patients, these values may be higher.
- Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate.
- The use of dexamfetamine is contraindicated in certain pre-existing cardiovascular disorders unless specialist cardiac advice has been obtained.
- Pre-existing structural cardiac abnormalities: Sudden death has been reported in association with the use of stimulants of the central nervous system at usual doses in children with structural cardiac abnormalities. Although some structural cardiac abnormalities alone may carry an increased risk of sudden death, stimulant products are not recommended in children, adolescents, or adults with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the onset of sympathomimetic effects of a stimulant medicine. Blood pressure should be monitored at appropriate intervals in all patients taking dexamfetamine, especially those with hypertension.

- Psychiatric adverse events:
  - Administration of stimulants may exacerbate symptoms of behaviour disturbance and thought disorders in patients with a pre-existing psychotic disorder.
  - Particular care should be taken in using stimulants in patients with comorbid bipolar disorder because of concern for possible induction of a mixed/manic episode in such patients.
  - Prior to initiating treatment with a stimulant, patients with comorbid depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder. Such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder and depression.
  - Treatment emergent psychotic or manic symptoms, e.g. hallucinations, delusional thinking or mania in patients without a prior history of psychotic illness or mania can be

caused by stimulants at usual doses. Aggression, suicidal ideation and onset or exacerbation of tics, anxiety, agitation or tension can also be associated with dexamfetamine. If such symptoms occur, consideration should be given to a possible causal role of the stimulant and discontinuation of treatment may be appropriate.

- Weight:
  - Moderately reduced weight gain and growth retardation have been reported with the long-term use of dexamfetamine in children. As a reduction in appetite may occur during treatment with dexamfetamine, the medicinal product may only be administered with special caution to patients with Anorexia nervosa.
- Epileptic patients:
  - Dexamfetamine should be used with caution in patients with epilepsy.
  - It may lower the convulsive threshold in patients with prior history of seizures, in patients with prior EEG abnormalities in the absence of seizures, and rarely in patients without a history of convulsions and no EEG abnormalities. If seizure frequency increases or new-onset seizures occur, dexamfetamine should be discontinued.

Initial monitoring:

ADHD:

- Before every change of dose: assess heart rate, blood pressure, and weight.
- After every change of dose: assess heart rate and blood pressure, appetite, weight and any new or worsening psychiatric symptoms
- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Narcolepsy:

- Blood pressure and pulse should be recorded during dose titration and then at least every 6 months.
- Psychiatric symptoms, appetite, weight and height should be recorded at initiation of therapy, following each dose adjustment and at least every 6 months thereafter.
- Monitor weight and appetite at each dose adjustment and at least 6 monthly.
- Monitor for development of de novo or worsening of pre-existing psychiatric disorders, including depression and aggressive behaviour at every dose adjustment and at least every 6 months.
- Patients should be monitored for the risk of diversion, misuse, and abuse of dexamfetamine.

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.

Ongoing monitoring (Narcolepsy):

Please advise

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
ADHD and Narcolepsy: • Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms • Weight 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 **Narcolepsy:** • Height	Every 6 months, and after any change of dose recommended by specialist team.
ADHD and Narcolepsy: • 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

• Review and ensure patient has been offered and attended review with healthcare professional with expertise in narcolepsy.	

(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.

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.

Result	Action for primary care
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	Stop dexamfetamine and discuss with specialist. Discontinuation may be indicated.
Anorexia or weight loss, weight or BMI outside healthy range	Exclude other reasons for 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.	Discuss with specialist. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present
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. Man agement 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 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/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 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
- 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. The specialist will reassume prescribing responsibility, ending the shared care agreement.

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, taking into account 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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Cambridgeshire and Peterborough NHS Foundation Trust:

Royal Papworth Hospital NHS Foundation Trust (Narcolepsy indication)

Respiratory support and sleep centre – Tertiary referral centre:

Specialist	Post	Telephone
Dr Ian E Smith	Medical Director of Royal Papworth Hospital and Consultant Sleep Physician	01223 639715
Dr Tim Quinnell	Director RSSC, Consultant Sleep Physician	01223 639718
Dr Mike Davies	Consultant Sleep Physician	01223 638571
Dr Nick Oscroft	Consultant Sleep Physician	01223 639803
Dr Martina Mason	Consultant Sleep Physician	01223 638401
Dr Dariusz Wozniak	Consultant Sleep Physician	01223 639619

Mr Duncan Grady	RSSC Directorate Pharmacist	01223 638700
Pharmacy Medicines Information Service	Non-Urgent Medicines Information for Clinicians engaging in dexamfetamine via shared Care	01223 638179
Pharmacy Medicines Helpline	Non-urgent Medicines Information for Patients receiving dexamfetamine via a shared care agreement	01223 638777 (answerphone)

For ADHD indication

Name: Cambridgeshire and Peterborough NHS Foundation Trust Adult Attention Deficit Hyperactivity Disorder (ADHD) clinic
Daytime telephone number: 01223 219674
Email address: *CPFTAdultADHDService@cpft.nhs.uk*

Name: CARE ADHD (Centre for ADHD Research & Excellence Ltd.)
Daytime telephone number: 020 4525 0709
Email address: *nhsreferrals@careadhd.co.uk*

Name: Harley Street Mental Health
Daytime telephone number: 0203 488 3655
Email address: *contact@hsmh.co.uk*

Name: Harrow Health ADHD Service
Daytime telephone number: 0203 989 6766
Email address: *harhl.adhdforms@nhs.net*

Name: Modality LLP
Daytime telephone number: 0300 0201 800
Email address: *m85178.modality.adhd@nhs.net*

Name: Skylight Psychiatry
Daytime telephone number: 0333 577 1996
Email address: *skylightpsych.adhdreferrals@nhs.net*

Name: The Owl Centre
Daytime telephone number: 01242 571883
Email address: *owl.rtc@nhs.net*

Name: Eton Psychiatrists
Daytime telephone number: 020 7929 2520
Email address: *Info@etonpsychiatrists.co.uk*

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 in writing of any changes to the patient's GP or their contact details.

15. References

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- NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via https://www.nice.org.uk/guidance/ng87/ on 04/05/21
- eBNF. Dexamfetamine, last updated 4th September 2020. Accessed via https://bnf.nice.org.uk/ on 04/05/2021
- Specialist Pharmacy Service. Safety in Lactation: Drugs for ADHD. Last updated October 2020. Accessed via https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/ on 05/05/2021
- Dexamfetamine sulfate 20 mg tablets (Amfexa®). Date of revision of the text: 14/01/21. Accessed via https://www.medicines.org.uk/emc/product/7404/smpc on 04/05/21
- Dexamfetamine sulfate 5mg tablets (Amfexa®). Date of revision of the text: 03/09/20. Accessed via https://www.medicines.org.uk on 04/05/21
- Dexamfetamine sulfate Prescribing Support (risk minimisation materials). Accessed via http://www.dexamfetamine-guide.co.uk/ on 11/05/21
- NICE. NG46: Controlled drugs: safe use and management. April 2016. Accessed via https://www.nice.org.uk/guidance/ng46/ on 05/05/2021
- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: Amfetamines. Last revised January 2021. Accessed via https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/amfetamines/ on 10/05/2021
- 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.

See Specialist Contact Information.

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.