Chile	dren and Young People Al	NHS	
Shar	red Care Protocol	Nottinghamshire Area Prescribing Committee	
V1.0	Last reviewed: January 2024	Review date: January 2027	

# Dexamfetamine for patients within children and young people services

Adapted from local adult ADHD shared care protocol which is based on the national adult template published by NHS England.

Traffic light classification-AMBER 1

The content of this shared care protocol was correct as of January 2024. Please ensure that <u>summaries of product characteristics</u> (SPCs), <u>British national formulary</u> (BNF) or the <u>Medicines and Healthcare products Regulatory Agency</u> (MHRA) or <u>NICE</u> websites are reviewed for up-to-date information on any medicine.



## **Children and Young People ADHD - Dexamfetamine Shared Care Protocol**

V1.0 Last reviewed: January 2024 Review date: January 2027

#### **Specialist responsibilities**

- Assess the patient and provide diagnosis. Ensure the diagnosis is within scope of this shared care protocol (<u>section 2</u>) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with
  the patient and/or their carer and provide the appropriate counselling (see <u>section 11</u>), to
  enable the patient to reach an informed decision. Obtain and document 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 <u>section 5</u>. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Prescribe in line with controlled drug prescription requirements (<u>section 6</u>).
- Once treatment is optimised, write to the patient's GP practice and request shared care, detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include the specialist service contact information (<u>section 13</u>).
   Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required monitoring in <u>section 8</u> 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.

#### **Primary care responsibilities**

- If shared care is not accepted, inform the specialist of the decision in writing within 14 days with reasons as to why shared care cannot be entered into.
- 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 (<u>section 6</u>).
- Adjust the dose of dexamfetamine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in <u>section 9</u>. Communicate any abnormal results to the specialist.
- Assess for possible interactions with dexamfetamine when starting new medicines (see section 7)
- Manage adverse effects as detailed in <u>section 10</u> 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. See <u>section 10</u>
- 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.
- Ensure the patient is given the appropriate appointments for monitoring. If a patient fails to attend, contact the patient in a timely manner and arrange an alternative appointment.

## Patient and/or carer responsibilities

- 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 <u>section 11</u>.

- 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.

## 1. Background Back to top

Dexamfetamine sulfate is a sympathomimetic amine with central stimulant and anorectic activity indicated for the treatment of attention deficit hyperactivity disorder (ADHD). The mode of therapeutic action of amfetamine in ADHD is not fully established, however is thought to be due to its ability to block the reuptake of noradrenaline and dopamine into the presynaptic neuron and increase the release of these monoamines into the extra neuronal space.

It may be offered as an alternative treatment in patients who have been appropriately diagnosed and as part of a comprehensive treatment program when response to previous methylphenidate treatment is considered clinically inadequate. It is recommended by NICE for patients whose symptoms are responding to lisdexamfetamine but are unable to tolerate the drug's longer effect profile (see <a href="NICE Guidance NG87">NICE Guidance NG87</a> 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.

Whilst <u>NICE guidance</u> state that medication can be prescribed from the age of 5, this is unlicensed and done with caution in exceptional circumstances by specialists therefore children < 6 years old are excluded from this shared care protocol. Patients ≥ 18 years old are covered by a separate <u>shared care protocol</u>.

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) or Community Paediatrics team but is approaching their 18th birthday, it is expected that CAMHS or Community Paediatrics team will refer to the appropriate adult service if need for ongoing treatment is anticipated. See the Nottinghamshire Area Prescribing Committee shared care protocol and medication information leaflets for adult ADHD at:

https://www.nottsapc.nhs.uk/shared-care/.

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.

2. Indications Back to top

Attention deficit hyperactivity disorder (ADHD) in children aged 6 years and over who are under the care of a specialist in childhood and/or adolescents behavioural disorders.

Whilst <u>NICE guidance</u> state that medication can be prescribed from the age of 5, this is unlicensed and done with caution in exceptional circumstances by specialists therefore children < 6 years old are excluded from this shared care protocol. Patients ≥ 18 years old are covered by a separate <u>shared care protocol</u>.

## 3. Locally agreed off-label use

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None identified

### 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 <u>BNF</u> & <u>SPC</u> for comprehensive information.

#### **Contraindications:**

- Known hypersensitivity to the active substance (dexamfetamine), 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 (consult specialist), 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 (see section 12)

#### Cautions:

- History of epilepsy. Stimulants may lower the convulsive threshold in patients with prior history of seizure. In the presence of new onset or worsening seizures (discontinue if seizures occur)
- Mild hypertension, history of cardiovascular disease, or concomitant medications that elevate blood pressure.
- Sudden death has been reported in children and adolescents taking CNS stimulants, including those with structural cardiac abnormalities or other serious heart problems. Not

for use in children or adolescents with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant medication.

- 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.
   Stimulants may exacerbate symptoms of behaviour disturbance and thought disorder in patients with pre-existing psychotic disorders
- Depressive symptoms: patients should be screened for risk of bipolar disorder, including psychiatric and family histories. Particular care should be taken in treating ADHD patients with comorbid bipolar disorder because of concern for possible induction of mixed/manic episodes in such patients.
- Treatment emergent pyschotic or manic symptoms can be caused by stimulants at usual doses. If these occur, consider the potential role of the stimulant, and discontinuation of treatment may be appropriate.
- Stimulants have been associated with a slowing of weight gain and a reduction in attained height. Monitor growth during treatment with stimulants.
- Renal and hepatic insufficiency (due to lack of data).
- Family history of sudden cardiac or unexplained death or malignant arrhythmia
- Breast-feeding (see <u>section 12</u>)
- 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 4 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 unless in the case of managing adverse effects as detailed in <u>section 10</u>

#### **Initial stabilisation:**

**ADHD**: Initially 5 mg once or twice daily, dose should be increased according to response at intervals no shorter than 1 week. Increasing, if necessary, by weekly increments of 5 mg in the daily dose according to tolerability and degree of efficacy observed.

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

#### Maintenance dose (following initial stabilisation):

ADHD: The maximum daily dose in children and adolescents is usually 20mg, although doses of 40mg may in rare cases be necessary`. The decision to give dexamfetamine once or twice daily should be based on the course of symptoms at different times of the day.

The initial maintenance dose must be prescribed by the initiating specialist. Specialist will inform GP on any subsequent doses. GPs should not alter any doses without discussing with specialist unless stopping due to side effects. See section 10.

Where a patient has been switched between medications (i.e. lisdexamfetamine to dexamfetamine) further monitoring may be required, as per specialist instruction.

#### **Duration of treatment**

Following an adequate treatment response, medication treatment for ADHD should be continued for as long as it remains clinically effective. This should be reviewed at least annually by the 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  Back to		
Route of administration:	Oral	
Formulation:	Dexamfetamine sulfate 5mg, 10mg and 20mg immediate rele (Amfexa®▼)  Dexamfetamine sulfate 5mg immediate release tablets  Dexamfetamine sulfate 5mg/5mL sugar-free oral solution▼ (release tablet)	
Administration details:	Tablets have score lines and can be divided into four parts. It the tablets is only to facilitate breaking for ease of swallowing into equal doses.  Dexamfetamine should not be taken too late after lunch time to disturbances of sleep  If a dose is missed then the next scheduled dose should be a double dose should not be taken to make up for a missed	g and not to divide to avoid se taken as usual;
Other important information:	Dexamfetamine is a schedule 2 controlled drug and is subject prescription requirements. It has the potential for misuse and Patients should be advised to avoid alcohol which may exace nervous system (CNS) side-effects of dexamfetamine. Dexam subject to additional monitoring by the Medicines and Healthous Regulatory Agency (MHRA) and healthcare professionals are report any suspected adverse reactions  Amfetamines can cause a significant elevation in plasma cort. This increase is greatest in the evening. Amfetamines may inturinary steroid determinations	diversion.  In the central of the ce

## 7. Significant medicine interactions

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The following list is not exhaustive. Please see <u>BNF</u> or <u>SPC</u> 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, isocarboxazid, moclobemide, phenelzine and tranylcypromine dexamfetamine should not be used in combination with MAOIs or within 2 weeks of stopping a MAOI due to risk of hypertensive crisis )
- 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.
- Coumarins: dexamfetamine may enhance the anticoagulant effect of warfarin. May require an increased frequency of INR monitoring.
- 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 thus increasing plasma levels of phenytoin and possibly primidone and phenobarbital.
- 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
- Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase
  is greatest in the evening.

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

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 <u>NICE guidance for ADHD</u>. This should include 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.
- Pre-treatment assessment to be performed will include diagnostic interview, behavioural rating scales (e.g., SDQ, Conners', CAARS self and observer report) and descriptive reports from parents and teachers.
- A risk assessment for substance misuse and drug diversion
- Height, weight (measured and recorded against normal range for age, height and sex),
   appetite and body mass index (BMI)
- Baseline blood pressure (BP) and heart rate(measured with appropriately sized cuff and compared with normal range for age

- A cardiovascular assessment.
  - An electrocardiogram (ECG) is not needed before starting, dexamfetamine unless the person has any features <u>below</u> or a co- existing condition being treated with a medicine that may pose an increased cardiac risk.
- Arrange for electrocardiogram (ECG) /echocardiogram /refer for cardiology opinion before starting medication, only if the patient has any of the following:
  - History of congenital heart disease or previous cardiac surgery
  - History of 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 that are rapid, regular and start and stop suddenly (fleeting occasional bumps are usually ectopic and do not need investigation)
  - Chest pain suggestive of cardiac origin
  - Signs of heart failure or heart murmur
  - Current treatment with a medicine that may increase cardiac risk
  - Blood pressure that is classified as hypertensive.

Refer to a paediatric hypertension specialist before starting a medication for ADHD if blood pressure is consistently above the 95<sup>th</sup> centile for age and height for children and young people. Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the Nottinghamshire Area Prescribing Committee website.

#### **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 as no standard is given in literature.
- 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 or electronic records such as System1 where available.

If the child / young person fails to attend for physical monitoring, despite attempts to reappoint, <u>do not</u> issue any further prescriptions, contact the patient/carer and inform the specialist. The patient should be informed of this policy when treatment begins.

## 9. Ongoing monitoring requirements to be undertaken by primary care

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

Monitoring	Frequency
Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms	Every 6 months, before and after any change of dose recommended by specialist team**.  Compare with previous measurements and with the normal range for age.  Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the Nottinghamshire Area Prescribing Committee website.  See section 10 for further guidance on management
<ul> <li>Assessment for new or worsening psychiatric and neurological signs or symptoms (e.g. tics, anxiety, symptoms of bipolar disorder)</li> <li>Explore whether patient is experiencing any difficulties with sleep</li> </ul>	Every 6 months, before and after any change of dose recommended by specialist team**.
Weight and appetite	Following initiation:

	<ul> <li>Every 3 months in children 10 years and under.</li> <li>Measure weight at 3 and 6 months after starting treatment in children over 10 years and young people and every 6 months thereafter, or more ofthen if concern arise.</li> <li>Plot on a growth chart (link:         <ul> <li>http://www.rcpch.ac.uk/growthcharts</li> </ul> </li> <li>If weight loss or reduced weight gain this should be discussed with the specialist.</li> </ul>
Height	Six monthly.  Plot on a growth chart.  If growth is affected significantly this should be discussed with the specialist.
Medication related side-effects*	At each visit
ECG, LFTs, FBC	Not recommended unless there is a clinical indication.
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

<sup>\*</sup>Consider using standard symptom and side effect rating scales during treatment as an adjunct to clinical assessment.

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.

<sup>\*\*</sup> The specialist should determine the appropriate timing for this monitoring as no standard is given in literature

## 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 <a href="https://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a>

For information on incidence of ADRs see relevant summaries of product characteristics

<u>European guidelines on managing adverse effects of medication for ADHD</u> were published in 2011. These provide additional guidance for clinicians.

IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE SPECIALIST TEAM.

If the child in front of you is acutely unwell, please contact the oncall general paediatric team

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.			
Sustained resting tachycardia arrhythmia/palpitations, clinically significant increase in systolic blood pressure is persistently above 95 th centile for age and height.	Withhold or reduce dose and review for acute additional symptoms. If present refer to general paediatric team. If no additional symptoms inform specialist and refer to a paediatric hypertension specialist as soon as possible  Information on blood pressure and heart rate monitoring in children (including centile reference tables) is available on the Nottinghamshire Area Prescribing Committee website.		
New or worsening seizures	Stop dexamfetamine and discuss with specialist team or oncall team immediately.		
Symptoms of cerebral ischaemia, e.g. severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory	Discontinue dexamfetamine, refer urgently for neurological assessment		

Anorexia or weight loss, weight or BMI outside healthy range	<ul> <li>Exclude other reasons for weight loss.</li> <li>Exclude other reasons for weight loss. Give advice as per NICE NG87:</li> <li>take medication with or after food, not before</li> <li>additional meals or snacks early in the morning or late in the evening when stimulant effects have worn off</li> <li>obtaining dietary advice</li> <li>consuming high-calorie foods of good nutritional value</li> <li>Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.</li> </ul>
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
Haematological disorders Including leukopenia, thrombocytopenia, anaemia related symptoms (e.g. paleness, lethargy) or other alterations Abnormal bruising / bleeding / severe sore throat / skin lesions or severe infection NB: no haematological monitoring is recommended. Haematological disorders would be a chance finding/due to patient reporting adverse drug reactions.	Seek immediate medical attention, not known to be related to dexamfetamine.
New or worsening psychiatric or neuropsychiatric symptoms, e.g psychosis, mania, aggressive or hostile behaviour, suicidal ideation or behaviour, motor or verbal tics (including Tourette's syndrome), anxiety,	Discuss with specialist. Stop treatment and consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present

agitation or tension, bipolar disorder, depression, paranoia, anxiety and agitation.  NB: psychosis may occur following consumption of very high doses.	
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue dexamfetamine and discuss with specialist team or oncall team immidiately.
Suspicion of abuse, misuse, or diversion	Discuss with specialist team
Failure to attend for physical monitoring checks	Do not issue further prescriptions, discuss as soon as possible with specialist.

## 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 <u>drugs and driving: the law.</u> People who drive must inform the DVLA if their ADHD, narcolepsy or medicines affect their ability to drive safely. See <a href="https://www.gov.uk/adhd-and-driving">https://www.gov.uk/adhd-and-driving</a> or <a href="https://www.gov.uk/narcolepsy-and-driving">https://www.gov.uk/narcolepsy-and-driving</a>.
- 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 <a href="https://www.rcpsych.ac.uk/mental-health/parents-and-young-people/information-for-parents-and-carers/ADHD-and-hyperkinetic-disorder-information-for-parents">https://www.rcpsych.ac.uk/mental-health/parents-and-young-people/information-for-parents</a>
   information-for-parents
- NHS Attention deficit hyperactivity disorder. <a href="https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/">https://www.nhs.uk/conditions/attention-deficit-hyperactivity-disorder-adhd/</a>
- https://www.youngminds.org.uk/
- https://youthmed.info/medicines/

## 12. Pregnancy, paternal exposure and breast feeding Back to top

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: <u>USE OF THERAPEUTIC AMFETAMINES IN PREGNANCY – UKTIS</u>

Patient information is available from <u>bumps - best use of medicine in pregnancy</u> (medicinesinpregnancy.org)

#### **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: <a href="https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/">https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/</a>

#### Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified.

## 13. Specialist contact information

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Child and Adolescent Mental Health Services (CAMHS 0115 8440500

Community Paediatrics ((Queens Medical Centre NUH) 0115 840 4848.

Community Paediatrics - Mansfield, Newark, Ollerton, Ashfield excluding Hucknall) at Sherwood Forest Hospitals NHS Foundation Trust

01623-622515

Nottinghamshire Healthcare NHS Foundation Trust Pharmacy advice line (for healthcare professionals): 0300 303 5808 and email: MI@nottshc.nhs.uk

Nottingham University Hospital QMC Pharmacy Medicines Information 0115 924 9924 Extension 84185/81200

Sherwood Forest Hospitals NHS Foundation Trust Pharmacy Medicine Information 01623-672213

Wells Road Centre Pharmacy Medicine information01159-555357

#### **Out of Hours**

Contact on-call CAMHS Psychiatrist via Nottinghamshire Healthcare NHS Foundation Trust 0118440500

**Oncall Paediatricians** 

Sherwood Forest Hospitals Trust – On call Paediatrician 01623 622 515

Nottinghamshire South (Nottingham University Hospital QMC) 0115-8831181 Nottinghamshire North (Sherwood Forest Hospitals NHS Foundation Trust) 01623-622515.

Other local NHS specialists may request shared care including local mental health teams and intellectual disability teams. The contact details for these teams will be detailed on the shared care request letter.

### 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 Back to top

 NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. Last updated September 2019. Accessed via <a href="https://www.nice.org.uk/guidance/ng87/">https://www.nice.org.uk/guidance/ng87/</a> 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 <a href="https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/">https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-for-adhd/</a> on 05/05/2021
- Dexamfetamine sulfate 20 mg tablets (Amfexa®). Date of revision of the text: 14/01/21.
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- Dexamfetamine sulfate 5mg tablets (Amfexa®). Date of revision of the text: 03/09/20.
   Accessed via <a href="https://www.medicines.org.uk">https://www.medicines.org.uk</a> 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 <a href="https://www.nice.org.uk/guidance/ng46/">https://www.nice.org.uk/guidance/ng46/</a> on 05/05/2021
- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: Amfetamines.
   Last revised January 2021. Accessed via <a href="https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/amfetamines/">https://cks.nice.org.uk/topics/attention-deficit-hyperactivity-disorder/prescribing-information/amfetamines/</a> on 10/05/2021
- Gov.uk. Drugs and driving: the law. Accessed via <a href="https://www.gov.uk/drug-driving-law">https://www.gov.uk/drug-driving-law</a> 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 <a href="https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/">https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/</a>
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <a href="https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care">https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care</a>
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

- Amfexa 5mg tablets, Flynn Pharma Ltd. Summary of product characteristics [ Last updated 10/02/2022] available at https://www.medicines.org.uk/emc/product/7403/smpc. Accessed 07/02//2023
- eBNFC Online, Last updated 14 December 2022. Accessed via <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a> on 07/02/2023
- Graham J et al. European guidelines on managing adverse effects of medication for ADHD.
   Eur Child Adolesc Psychiatry (2011),20:17-37. On-line at http://www.springerlink.com/content/y667034856017253/fulltext.pdf
- Nottinghamshire Area Prescribing Committee. September 2020. Blood pressure and heart rate monitoring in children. Information Sheet for Primary Care Prescribers. Available from <a href="https://www.nottsapc.nhs.uk/media/1627/bp\_and\_hr\_monitoring\_for\_children.pdf">https://www.nottsapc.nhs.uk/media/1627/bp\_and\_hr\_monitoring\_for\_children.pdf</a>.

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## 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.

- Prescribing and monitoring responsibility will only be transferred when the patient's condition and medication are stable.
- The specialist will request shared care with the GP in writing.
- If the GP doesn't agree to shared care, they should inform the specialist of their decision in writing within 14 days.
- In cases where shared care arrangements are not in place or where problems have arisen within the agreement and patient care may be affected, the responsibility for the patients' management including prescribing reverts back to the specialist.
- Should the patient's condition change, the GP should contact the relevant specialist using the details provided with the shared care request letter.