

National shared care protocol: Adapted for use as WY ICS amber guidance

Lisdexamfetamine for patients within adult services

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 communicated to patient's GP.
- 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 informed consent in line with current local processes. Provide an appropriate patient information leaflet.
- Discuss with the patient their responsibilities outlined below, confirm understanding, and confirm that the patient is happy to adhere to them
- 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.

- Prescribe in line with controlled drug prescription requirements ([section 6](#)).
- Send information to the patient's GP practice detailing the current and ongoing dose including brand and formulation, any relevant test results and when the next monitoring is required. Provide a link or a copy of the most up to date amber guidance to the patient's GP practice.
- Prescribe sufficient medication to enable transfer to primary 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.
- Inform patient's GP if review date has exceeded 18 months, to stop treatment.
- Provide advice to primary care on the management of adverse when requested. This should be ongoing until the patient ceases to be on lisdexamfetamine.

Primary care responsibilities

- Respond to the specialist in writing within 2 weeks if unwilling to take over prescribing and monitoring as requested by specialist. Include rationale for unwilling to take over prescribing.
- 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 lisdexamfetamine 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 lisdexamfetamine when starting new medicines (see [section 7](#))
- Manage adverse effects as detailed in [section 10](#) and discuss with specialist team when required.
- Stop lisdexamfetamine and make an urgent referral for appropriate care if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected.

- Refer the management to local perinatal service if the patient becomes or plans to become pregnant
- Stop treatment as advised by the specialist. Trial discontinuations should be managed by the specialist.

Patient and/or carer responsibilities

- To agree and accept responsibility for taking lisdexamfetamine as prescribed.
- To understand how to take lisdexamfetamine safely.
- To understand the duration of treatment prescribed initially by the hospital specialist.
- To understand the most common adverse events/side effects and inform the Specialist/GP as soon as reasonably possible should they occur and significantly affect the use of the medicines.
- Report suspected adverse effects to the Medicines and Healthcare products Regulatory Agency. <https://yellowcard.mhra.gov.uk/>
- To understand the circumstances under which the medicines should be immediately stopped and what action to take.
- To understand contents of written information provided by the Specialist and in the patient information leaflet supplied with the medicines and to seek clarification if required.
- To attend for blood tests/disease monitoring on time.
- To check with the community pharmacist that there are no interactions with lisdexamfetamine, and other medications taken including other prescribed medications, medicines bought over the counter and herbal/homoeopathic products.
- To check with dentists or other specialists who may prescribe medicines that there are no interactions with lisdexamfetamine.
- Be aware that lisdexamfetamine 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 during treatment, as it may make some side effects worse. Avoid recreational drugs. Lisdexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions and should store lisdexamfetamine safely and securely. It must not be shared with anyone else.
- To read the information supplied by the GP, specialist, pharmacist, or other healthcare professional, and contact the relevant practitioner if they do not understand any of the information given.

- More information on asking about medication can be found in the Me & My Medicines Charter <https://meandmymedicines.org.uk/the-charter/>
- Use an appropriate form of contraception, as agreed with their doctor/nurse/sexual health service.
- Inform the specialist or primary care prescriber immediately if they become pregnant or wish to become pregnant.
- The NHS Website – NHS information on health [link](#) and medicines [link](#)
- Patient information leaflets for mental health conditions and treatments: Leeds and York Partnership NHS Foundation Trust
<https://www.choiceandmedication.org/leedsandyorkpft>
- South West Yorkshire Partnership NHS Foundation Trust
<https://www.choiceandmedication.org/swyp/>
- Bradford District Care NHS Foundation Trust
<https://www.choiceandmedication.org/bradford>

1. Background

[Back to top](#)

Lisdexamfetamine dimesylate is metabolised following administration to dexamfetamine and therefore has the same sympathomimetic mechanism of action with central stimulant and anorectic activity. It is indicated as part of a comprehensive treatment programme for the treatment of attention deficit hyperactivity disorder (ADHD) when the response to a 6-week trial of methylphenidate treatment is considered clinically inadequate. It may be offered as a first line pharmacological treatment option for adults with ADHD who have been appropriately diagnosed (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.

Lisdexamfetamine 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.

Pharmacological treatment of ADHD may be needed for extended periods. When lisdexamfetamine is used for extended periods (over 12 months) its usefulness should be re-evaluated at least yearly by a healthcare professional with expertise in ADHD, and consideration given to trial periods off medication to assess the patient's functioning without pharmacotherapy.

2. Indications

[Back to top](#)

Licensed indication: attention deficit hyperactivity disorder (ADHD) in adults
See [SPC](#) for full details of licensed indication.

3. Locally agreed off-label use

[Back to top](#)

Nil

4. Contraindications and cautions

[Back to top](#)

Please see [BNF](#) & [SPC](#) for comprehensive information.

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5. Initiation and ongoing dose regimen

[Back to top](#)

- Transfer of monitoring and prescribing to primary care is normally after 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:

30 mg taken once daily in the morning, increased in increments of 20 mg at intervals no shorter than 1 week. Lower starting doses may be used if clinically appropriate (off-label use).

The loading period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

Maximum 70 mg per day.

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

Conditions requiring dose adjustment:

In severe renal impairment (GFR 15-30mL/min/1.73m² or CrCl less than 30mL/min), the recommended maximum dose is 50 mg per day.

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 GP of the outcome.

6. Pharmaceutical aspects

[Back to top](#)

Route of administration:	Oral
Formulation:	Lisdexamfetamine dimesylate 30mg 50mg and 70mg hard capsules (Elvanse Adult®) Lisdexamfetamine dimesylate 20mg, 30mg, 40mg, 50mg, 60mg and 70mg hard capsules (Elvanse®) – use in adults may be considered off-label. See SPC for full details.
Administration details:	The dose may be taken with or without food Lisdexamfetamine capsules may be swallowed whole, or the capsule opened, and the entire contents emptied and mixed with a soft food such as yogurt or in a glass of water or orange juice. See SPC for further information If a dose is missed, then the next scheduled dose should be taken as usual; <u>a double dose should not be taken to make up for a missed dose</u> . Afternoon doses should be avoided because of the potential for insomnia

Other important information:	<p>Lisdexamfetamine is a schedule 2 controlled drug and is subject to legal prescription requirements. It has the potential for misuse and diversion.</p> <p>Patients should be advised to avoid alcohol which may exacerbate the central nervous system (CNS) side-effects of lisdexamfetamine</p> <p>Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amfetamines may interfere with urinary steroid determinations</p>
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7. Significant medicine interactions

[Back to top](#)

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 or other healthcare professional with expertise in ADHD:

- **Mono-amine oxidase inhibitors (MAOIs) and other sympathomimetics** (e.g., rasagiline, selegiline, safinamide) – additive hypertensive effect

Other clinically significant interactions

- **Selective serotonin reuptake inhibitors (SSRIs) (e.g., fluoxetine, paroxetine):** may increase exposure to lisdexamfetamine, risk of serotonin syndrome
- **Serotonergic drugs, bupropion, tapentadol, tramadol:** Risk of serotonin syndrome
- **Tricyclic antidepressants (TCAs) and nabilone:** may increase risk of cardiovascular adverse events.
- **Ascorbic acid and other agents and conditions (thiazide diuretics, diets high in animal protein, diabetes, respiratory acidosis)** that acidify urine increase urinary excretion and decrease the half-life of amfetamine.
- **Sodium bicarbonate and other agents and conditions (diets high in fruits and vegetables, urinary tract infections and vomiting)** that alkalinise urine decrease urinary excretion and extend the half-life of lisdexamfetamine.
- **Antihypertensives, including guanethidine:** effects may be reduced by lisdexamfetamine
- **Lithium, phenothiazines, haloperidol:** may reduce the effects of lisdexamfetamine

- **Opioids** (including tapentadol and tramadol): analgesic effects may be increased by lisdexamfetamine
- **Alcohol:** Limited data is available; therefore, caution is advised as alcohol may exacerbate the CNS side effects of lisdexamfetamine
- **Apraclonidine:** effects decreased by lisdexamfetamine.
- **Ritonavir, tipranavir:** may increase exposure to lisdexamfetamine
- **Safinamide:** predicted to increase the risk of severe hypertension when given with lisdexamfetamine
- **Atomoxetine:** increased risk of adverse effects

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 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
- Weight and body mass index (BMI)
- Arrange for electrocardiogram (ECG), only if the patient has any of the following:
 - History of congenital heart disease or previous cardiac surgery
 - Sudden death in a first-degree relative under 40 years suggesting a cardiac disease
 - Shortness of breath on exertion compared with peers
 - Fainting on exertion or in response to fright or noise
 - Palpitations
 - Chest pain suggestive of cardiac origin

- Signs of heart failure, heart murmur or hypertension
- Current treatment with a medicine that may increase cardiac risk

Initial monitoring:

- Before every change of dose: assess heart rate, blood pressure, and weight.
- After every change of dose: assess heart rate and blood pressure, and any new or worsening psychiatric symptoms. The specialist should determine the appropriate timing for this monitoring.
- Monitor for aggressive behaviour or hostility
- Assessment of symptom improvement. Discontinue if no improvement is observed after one month.

Follow Up (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

[Back to top](#)

See [section 10](#) for further guidance on management of adverse effects/responding to monitoring results.

Monitoring and advice	Frequency
<ul style="list-style-type: none"> • Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms 	Every 6 months, and 1-2 weeks after any change of dose recommended by specialist team.

<ul style="list-style-type: none"> • 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 	
<ul style="list-style-type: none"> • Assessment of adherence, and for any indication of lisdexamfetamine abuse, misuse, or diversion 	As required, based on the patient's needs and individual circumstances
<ul style="list-style-type: none"> • Review to ensure patient has been offered and attended an annual review with a healthcare professional with expertise in ADHD 	Annually
<p>(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.</p>	
<p>10. Adverse effects and other management Back to top</p> <p>Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard</p> <p>For information on incidence of ADRs see relevant summaries of product characteristics</p>	
Result	Action for primary care
<p>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.</p>	

Pulse - if pulse >120bpm on at least two occasions 1-2 weeks apart	contact specialist for advice
Blood pressure – if BP >140/90 on two occasions 1-2 weeks apart	contact specialist for advice if remains raised
New or worsening seizures	Stop treatment and discuss with specialist. Permanent discontinuation may be indicated.
Anorexia or weight loss, weight, or BMI outside healthy range	<p>Exclude other reasons for weight loss. Exclude other reasons for weight loss. Give advice as per NICE NG87:</p> <ul style="list-style-type: none"> • 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 <p>Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be required.</p>
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	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 lisdexamfetamine as soon as possible. Management depends on severity; use clinical judgement and seek advice if necessary. Discuss with specialist team to determine whether lisdexamfetamine can be re-started.
Suspicion of abuse, misuse, or diversion	Discuss with specialist team

11. Advice to patients and carers

[Back to top](#)

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/carers 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
- Any visual changes such as difficulty with accommodation or blurring of vision
- 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.
- Lisdexamfetamine 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 or medicines affect their ability to drive safely. See <https://www.gov.uk/adhd-and-driving>
- Avoid alcohol while taking lisdexamfetamine, as it may make some side effects worse. Avoid recreational drugs. Due to the risks of severe depression, and fatigue, abrupt withdrawal after a prolonged period of intake of high doses of lisdexamfetamine should be avoided. Patients wishing to reduce their dose or stop lisdexamfetamine treatment should discuss with their specialist before doing so.
- Lisdexamfetamine is a schedule 2 controlled drug. Patients may be required to prove their identity when collecting prescriptions and should store lisdexamfetamine 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/>

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:

The active metabolite of lisdexamfetamine, dexamfetamine, is thought to cross the placenta. The limited data available shows an increased risk of premature birth and preeclampsia. 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. Lisdexamfetamine 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:

There is no published evidence for safety of lisdexamfetamine in breastfeeding. The manufacturers recommend against use, and the UK Drugs in Lactation Service recommend caution (see link below). Lisdexamfetamine metabolites, including dexamfetamine, are excreted in human milk, therefore a risk to infants cannot be excluded. An individual risk assessment must be made, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

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

[Back to top](#)

See specialist letter for details

Bradford District Care NHS Foundation Trust

phone number and e-mail: 01274 363 230

pharmacy@bdct.nhs.uk

BANDS team
Horton Park centre
CITY CMHT
99 Horton Park Avenue
Bradford

Leeds and York Partnership Foundation Trust

Leeds phone number and e-mail: 0113 8555534

Pharmacyleedspft.lypft@nhs.net

South West Yorkshire Partnership Foundation Trust

Team	Email Address	Contact number
Wakefield	FieldheadPharmacy@swyt.nhs.uk	01924 316820
Barnsley	KendrayPharmacyTeam@swyt.nhs.uk	01226 644338 or 644145
Calderdale	PharmacyTeamCK@swyt.nhs.uk	01422 222933
Huddersfield		01484 343108
Dewsbury		01924 316374

website address for SWYPFT ADHD team

[Adult attention deficit hyperactivity disorder \(ADHD\) service - South West Yorkshire Partnership NHS Foundation Trust](#)

And here is the email

ADHDandAutismService@swyt.nhs.uk