BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	**Lisdexamfetamine dimesylate (Elvanse®)**
Amber ***three months***	
Indication	Part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD) in children and young people of 5*years and over, where: • Methylphenidate treatment has been considered to be: ○ Clinically inadequate (symptoms have not responded to adequate trials of methylphenidate.) ○ Not tolerated ○ Contraindicated ○ Inappropriate (e.g. concerns about misappropriation of stimulants). *Lisdexamfetamine is licenced from 6 years, 'off-label' use for 5 year old patients but supported by NICE Guideline (NG87; 1.5.13).

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	Lisdexamfetamine is a stimulant. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or ADHD specialist non-medial prescriber. **Dose:** Initially 20-30 mg once daily, dose to be taken in the morning. Dose increased in steps of 10–20 mg every week if needed, to a maximum of 70 mg per day. Lisdexamfetamine is classed as a schedule 2 Controlled Drug under the Misuse of Dugs Regulations 2001 (MDR). Prescriptions must therefore conform to the MDR. **It is 'best practice' and AWP procedure to prescribe one month supply or less of any schedule 2 controlled drugs at a time.**

Route and formulation	Oral Elvanse® 20mg, 30mg, 40mg, 50mg, 60mg and 70mg capsules
Duration of treatment	Lisdexamfetamine should be continued for as long as it is effective.

	Discontinue after 4-6 weeks if insufficient response at maximum tolerated dose.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate

Monitoring at baseline and during initiation is the responsibility of the specialist; once the patient is optimised on the chosen medicine, with no anticipated changes expected in the immediate future, prescribing will be transferred to the GP. Monitoring will remain the with the specialist clinician in secondary care unless specific arrangements are made with GP. Patients will be reviewed by a specialist clinician annually as a minimum.

Baseline investigations include:

- Cardiovascular status including blood pressure, heart rate, height and weight on growth chart (see table below).
- Comprehensive history of concomitant medicines (past and present), co-morbid physical and psychiatric disorders or symptoms, and family history of sudden cardiac/unexplained death.
- Assessment of risk of diversion and/or misuse.

Blood tests, ECG and other parameters are not required unless specifically indicated for individual patients.

Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Test	**Frequency**	**Who by**	**Action/management** **For paediatric patients the use of a centile chart is recommended**
Blood pressure (BP), pulse, weight, height	Prior to medication initiation	Initiating clinician (CAMHS* or Community Paediatrics department)	To prepare for medication titration
BP	After each dose increase, every 6 months and at annual review	CAMHS or Community Paediatrics department unless local arrangements have been made for individual patients (can also be managed by primary care under	Compare with normal range for age, if there is a clinically significant increase in blood pressure or systolic blood pressure is greater than 95th percentile (measured on 2 occasions), refer to paediatric hypertension specialist; consider dose adjustment or alternative ADHD treatment.
Pulse			Compare with normal range for age. NICE guidance suggests to

		advice from secondary care)	investigate a resting tachycardia of > 120bpm; we suggest to monitor and possibly investigate a sustained resting tachycardia >100bpm; consider ECG; discuss with paediatric physical health colleagues as needed.
Height	Every 6 months		Plot height and weight of children and young people on a growth chart and ensure review by clinician responsible for treatment.
Weight	**Children 10 years and under:** 3 monthly **Children over 10 years and young people:** 3 and 6 months following initiation and 6 monthly thereafter *More often if concerns arise.*		If there is evidence of significant weight loss or nil weight gain where expected, measure BMI and discuss with patient and family/ carer as appropriate. Strategies to manage weight loss include: -Taking medication with or after food -Additional meals/snacks early morning or late evening when stimulant effects have worn off -Choosing high calorie foods of good nutritional value -Taking a planned break from treatment or changing medication. Plot height and weight of children and young people on a growth chart and ensure review by clinician responsible for treatment.
Assessment of adherence and monitoring for effectiveness and adverse effects including suicidal ideation or behaviour, tics, sexual dysfunction, seizures and sleep.	After each dose adjustments, every 6 months, at annual review and as required based on the patient's needs and individual circumstances.	CAMHS or Community Paediatrics department unless local arrangements have been made for individual patients (can also be managed by primary care under advice from secondary care)	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 rationale. Seek secondary care advice. With stimulant medication, this should include review of potential misuse and diversion.

*Children and Adolescent Mental Health Service

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management

Side effect	Frequency	Action/management
Headache	Very Common	Usually transient. If it is persistent, consider stopping and consult the specialist team
Decreased Appetite	Very Common	Take medication after breakfast/food; Maximise food intake at times of least appetite suppression; increase snacking, introduce liquid calories (smoothies etc.)
Dry Mouth	Very Common	Contact specialist if persists
Insomnia	Very Common	This may be transient. Make sure medication is taken in the morning. Refer to the specialist team if persistent
CVS Symptoms: arrhythmias, tachycardia, hypertension, palpitations	Common	Monitor the BP, pulse, and if necessary perform an ECG. If the resting pulse is consistently > 100bpm, contact the specialist team (consideration must be given to child/young person's age and what is expected for age)
Agitation, anxiety, bruxism, restlessness, tremor, irritability, dizziness	Common	Common on initiation. Often subsides after several days. If no improvement, consult specialist
Reduced libido, erectile dysfunction	Common	Contact specialist
Dyspnoea	Common	Contact specialist if persists
GI disorders – diarrhoea, constipation, nausea, vomiting, abdominal pain	Common	Contact specialist if persists
Difficulties in visual accommodation	Rare	Usually transient. Optician to check to rule out other causes such as increased intraocular pressure. Contact specialist team if persistent
Serotonin Syndrome	Rare	Can occur when co-prescribed with antidepressants and lithium; stop Lisdexamfetamine immediately if suspected and seek expert advice. Early symptoms of serotonin syndrome include tachycardia, shivering, diarrhoea, diaphoresis, muscle cramps, agitation, and elevated body temperature
Leukopenia, thrombocytopenia and anaemia	Rare	Refer to specialist team, medicine may need to be stopped

Effects on ability to drive and use machines Lisdexamfetamine can cause dizziness, drowsiness and transient visual disturbances including difficulties with

	accommodation, diplopia and blurred vision (rare). It may have a moderate influence on the ability to drive and use machines. This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:
	• The medicine is likely to affect your ability to drive
	• Do not drive until you know how the medicine affects you
	• It is an offence to drive while under the influence of this medicine
	• However, you would not be committing an offence (called 'statutory defence') if:
	  ○ The medicine has been prescribed to treat a medical problem and
	  ○ You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and
	  ○ It was not affecting your ability to drive safely.

Referral back to specialist	Contact specialist for advice if: • There is a query regarding medication efficacy • Patient finds the medication intolerable for any given reason • If there is concern about observed mental/psychological or physical side effects (e.g. depression or hypertension) • The side effects mentioned above, do not appear to be of a temporary and short-lived nature and they persist • If patient is pregnant or breastfeeding

Section 5: Other Issues

(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues

Significant Drug Interactions

MAOIs	E.g. moclobemide; risk of hypertensive crisis. Not to be given within 2 weeks of MAOIs.
Tricyclic antidepressants	Increased levels of TCA as can inhibit metabolism
Urinary PH altering agents	E.g. Ascorbic acid, thiazide diuretics and sodium bicarbonate. Agents that acidify urine increase urinary excretion and decrease the half-life of Lisdexamfetamine, decreasing over all levels of amphetamine. Agents that alkalinise urine decrease urinary excretion and extend half-life, increasing overall levels of amphetamine.
Antipsychotics and other dopaminergic drugs	E.g. Chlorpromazine and haloperidol block dopamine and norepinephrine receptors, thus inhibiting the central stimulant effects of Lisdexamfetamine.
Antihypertensives	Lisdexamfetamine may reduce the effect of antihypertensives.
Alcohol	Limited data, may increase CNS adverse reactions.
Serotonergic drugs	Potential increased risk of serotonin syndrome with co-administration – monitor and discontinue lisdexamfetamine as soon as possible if suspected.
Lithium	Anorectic and stimulatory effects of amfetamines may be inhibited by lithium carbonate
Steroids	Amfetamines can cause significant elevation in plasma corticosteroid levels. Greatest increase in the evening.

	<table><tr><td>Others</td><td>Use with caution with other sympathomimetics e.g. pseudoephedrine and decongestants.</td></tr></table> **Contraindications** • Hypersensitivity to sympathomimetic amines or any of the excipients in the particular formulation • Concomitant use of monoamine oxidase inhibitors (MAOIs) or within 14 days after treatment (due to the risk of hypertensive crisis). • Hyperthyroidism or thyrotoxicosis • Agitated states • Symptomatic cardiovascular disease • Advanced arteriosclerosis • Moderate to severe hypertension. • Glaucoma **Special Warnings and precautions** • Pre-existing cardiovascular disorders including serious structural abnormalities, cardiomyopathy, serious heart rhythm abnormalities, pre-existing hypertension, coronary artery disease or heart failure • Pre-existing cerebrovascular disorders cerebral aneurysm, vascular abnormalities including vasculitis or stroke or known risk factors for cerebrovascular disorders • Diagnosis or history of recent severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder • Diagnosis or history of severe and episodic (Type 1) Bipolar (affective) disorder • Tics – stimulants can exacerbate motor and phonic tics and Tourette's Syndrome • Aggression – stimulants may cause aggressive behaviour or hostility • Seizures – stimulants may lower the seizure threshold • Pregnancy – Seek specialist advice • Breast-feeding – Seek specialist advice • Dose reduction is required in severe renal impairment – seek specialist advice. **Dose reduction and discontinuation** If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued – advice should be sought from the specialist. Patients should be carefully monitored for the risk of diversion, misuse and abuse of lisdexamfetamine. Lisdexamfetamine should be used with caution in patients with known drug or alcohol dependency because of a potential for abuse, misuse or diversion.
Reminder to ask patient about specific problems	Ask about emergence of any possible side effects/compliance to treatment issues

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

The patient and/or family/carer should be advised:

1. It is not advisable to drink alcohol, use recreational substances or consume excessive amounts of caffeine whilst taking Lisdexamfetamine.
2. The patient should immediately report abdominal pain, unexplained nausea, malaise, darkening of the urine, jaundice, or suicidal thinking and/or self-harm to the GP.
3. Failure to attend annual reviews could result in the medication being stopped.
4. Patients can choose to try stopping the medication. Annual reviews are an ideal opportunity to discuss this but a desire to stop medication can be expressed and discussed at any time.
5. Information on drug prescribed including a patient information leaflet (PIL). Information on mental health conditions, treatments and medication can be found at:

Choice and Medication
NHS – Attention Deficit Hyperactivity Disorder
Medicines for Children leaflet: Lisdexamfetamine for ADHD
Lisdexamfetamine Patient Information Leaflet

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Communicate changes of medication form, strength or dose to the GP before the next repeat prescription is due (i.e. within 28 days). Note that a change of dose does not itself imply instability, and is usually done as a response to patient growth. If the secondary care clinician feels the medication is not at a stable dose, the GP will be informed that the secondary care provider will supply medication until this is again stable
5. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
6. To provide advice to primary care when appropriate.
7. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
8. Stopping treatment where appropriate or providing advice on when to stop.
9. Reporting adverse events to the MHRA.
10. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 9: Contact Details

Name	Organisation	Telephone Number	E mail address
Initiating Clinician	AWP/Sirona	As provided on correspondence	As provided on correspondence
Sarah Steel Highly Specialised Clinical Pharmacist	AWP	01249 474542	Sarah.steel6@nhs.net

Section 10: Document Details

Date prepared	28th April 2023
Prepared by	Sarah Steel
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Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Sarah Steel highly specialised clinical pharmacist AWP
2. Samantha Hayer CAMHS consultant AWP
3. Alfred Perrera CAMHS consultant AWP
4. Richard Williams Consultant Paediatrician Sirona Care & Health
5. Richard Lee-Kelland, Consultant Community Paediatrician Sirona Care & Health – from June 2023

Section 12: References

Please list references

1. NICE Guideline [NG87]. Attention Deficit Hyperactivity Disorder: diagnosis and management. Updated 13.09.2019. Accessed Feb 2023.
2. SPC Lisdexamfetamine. Updated 14.11.2022. Accessed Feb 2023.
3. BNF Online. Lisdexamfetamine. Updated September 2022. Accessed Feb 2023.
4. Cortese S, *et al.* Pharmacological and non-pharmacological interventions for adults with ADHD: protocol for a systematic review and network meta-analysis *BMJ Open*. Accessed May 2023.