

# Surrey Heartlands Integrated Care System Area Prescribing Committee (APC)

# **AMBER** shared care protocol:

# Lisdexamfetamine

To treat symptoms of ADHD in children aged 6 and over in "Cohort 2" (See Appendix 4), who have a concurrent mental health or neurodevelopmental condition requiring specialist care or where their condition is not considered to be sufficiently stable for discharge to primary care, and where the primary care provider is participating in the Locally Commissioned Service (LCS) for ADHD

Review date - May 2027

### **Specialist responsibilities**

- Assess the patient and provide diagnosis; ensure that this 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 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.
- Assess for contraindications and cautions (see <u>section 4</u>) and interactions (see <u>section 7</u>).
- Conduct required baseline investigations and initial monitoring (see <u>section 8</u>).
- Initiate and optimise treatment as outlined in section 5.
- Transfer to primary care is normally after the patient has been treated at the maintenance dose for 2 months and with satisfactory investigation results for at least 4 weeks. Prescribe sufficient medication (one month's supply) to enable transfer to primary care, including where there are unforeseen delays to transfer of care. Check product details for pack sizes as most products manufactured in boxes of 28 dose units.
- Prescribe in line with controlled drug requirements (<u>Section 6</u>)
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, baseline and most recent test results, confirm the monitoring schedule and when the next monitoring is required.
   Include contact information (section 13).
- Conduct the required monitoring in <u>section 8</u> and communicate the results to primary care.
   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.
- Reassume prescribing responsibilities if the patient becomes or wishes to become pregnant.
- Reassume prescribing responsibilities if the patient develops a concurrent mental health or neurodevelopmental condition requiring specialist care where their ADHD is best managed by the specialist service
- Provide advice to primary care on the management of adverse effects if required.
- Advise primary care if treatment should be discontinued. Trial discontinuations can be supported by the specialist.

### **Primary care responsibilities**

- Respond to 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 any account potential drug interactions in section 7.
- Adjust the dose of lisdexamfetamine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9.
- Assess for possible interactions with lisdexamfetamine when starting new medicines (see section 7).
- Manage any adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop lisdexamfetamine and make an urgent referral to the specialist if cerebral ischaemia, new or worsening seizures, or serotonin syndrome are suspected.
- Discuss other adverse effects with the specialist team as clinically appropriate (see section 10).
- 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.

# Patient and/or carer responsibilities

- Not to drive, use other modes of transport that require a high level of alertness e.g. bicycle, scooter, operate machines or undertake skilled tasks if lisdexamfetamine affects their ability to do so safely, e.g. by causing dizziness, drowsiness, or visual disturbances
- Avoid alcohol while taking lisdexamfetamine, as it may make side effects worse. Avoid recreational drugs.
- Take lisdexamfetamine as prescribed and do not stop taking it without speaking to their primary care prescriber or specialist.
- Lisdexamfetamine is a schedule 2 controlled drug. Patients, their family or carer 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. Note that where a child (under 16) presents to a pharmacy to collect their medication, pharmacists will need to decide whether to provide it to them, or request that a family member or carer collects the medicine, based on the individual circumstances.

- Tell anyone who prescribes them a medicine that they are taking lisdexamfetamine
- Attend regularly for monitoring and review appointments with primary care and specialist. Failure to attend appointments may result in cessation of treatment and review of ongoing provision of care, with a possibility of discharge from the service.
- 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 GP and be aware they should discuss the use of lisdexamfetamine with their pharmacist before purchasing any OTC medicines.

People of child-bearing 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 are planning a pregnancy

# 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 to children aged 5 years and over and young people who have had a 6-week trial of methylphenidate at an adequate dose and not derived enough benefit in terms of reduced ADHD symptoms and associated impairment. (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 reevaluated 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

Attention deficit hyperactivity disorder (ADHD) in children aged 6 years and over when response to previous methylphenidate treatment is considered clinically inadequate

# 3. Locally agreed off-label use

Back to top

The Surrey Heartlands Integrated Care System Area Prescribing Committee recommended the use of this document for the indications as outlined above.

The following information should be provided in correspondence to support prescribing in line with this shared care.

- Dosing specific to the indication
- Relevant interaction information
- Any additional monitoring requirements over and above the shared care.
- Duration of treatment
- Frequency of review.
- Specific features of adverse effects or deterioration pertinent to the specific indication for which it is used

### 4. Contraindications and cautions

Back to top

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.
- Symptomatic cardiovascular disease.
- Moderate or severe hypertension.
- Advanced arteriosclerosis.
- Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of MAOI
- treatment.

- Hyperthyroidism or thyrotoxicosis.
- Agitated states.

#### Cautions:

- History of substance or alcohol abuse.
- Cardiovascular disorders such as structural cardiac abnormalities, cardiomyopathy, arrhythmias, coronary artery disease, mild hypertension, recent myocardial infarction, or heart failure.
- Family history of sudden cardiac or unexplained death, ventricular arrhythmia, tics or Tourette's syndrome.
- Underlying medical conditions or concomitant drugs which can increase the QT-interval or heart rate, or elevate blood pressure (e.g. cardiac disease, electrolyte disturbance).
- History of seizure disorders (discontinue if seizures occur).
- Susceptibility to angle-closure glaucoma.
- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour), tics, Tourette's syndrome, anxiety, or bipolar disorder.
- Depressive symptoms: patients should be screened for risk of bipolar disorder, including psychiatric and family histories.
- Severe renal impairment; GFR 15-30mL/min/1.73m2 or CrCl less than 30mL/min, or according to criteria for child's age. Dose reduction is required, see section 5.
- Hepatic insufficiency (due to lack of data).
- Pregnancy or breast-feeding (see section 12).
- Potential for abuse, misuse, or diversion.

# 5. Initiation and ongoing dose regimen

Back to top

- 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:**

### Recommended starting dose in ADHD:

The starting dose is 30 mg taken once daily in the morning. When in the judgment of the clinician a lower initial dose is appropriate, patients may begin treatment with 20 mg once daily in the morning.

The stabilisation period must be prescribed by the initiating specialist.

### Maintenance dose (following initial stabilisation):

The dose may be increased by 10 or 20 mg increments, at approximately weekly intervals. Lisdexamfetamine should be administered orally at the lowest effective dosage.

#### Maximum dose in ADHD in children

The maximum recommended dose is 70 mg/day; higher doses have not been studied; consult BNF and SPC.

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, their family or carer, and GP of the outcome.

6. Pharmaceutical aspects		Back to top
Route of administration:	Oral	

Formulation:	Lisdexamfetamine dimesylate 20mg, 30mg, 40mg, 50mg, 60mg and 70mg hard capsules (Elvanse®)
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; a double dose should not be taken to make up for a missed dose. Afternoon doses should be avoided because of the potential for insomnia.
Other important information:	Lisdexamfetamine is a schedule 2 controlled drug and is subject to prescribing restrictions and 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 lisdexamfetamine. Lisdexamfetamine is subject to additional monitoring by the Medicines and Healthcare products Regulatory Agency (MHRA) and healthcare professionals are encouraged to report any suspected adverse reactions  Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amfetamines may interfere with urinary steroid determinations.

# 7. Significant medicine interactions

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:

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.

#### Pre-treatment: (Specialist Clinician)

- 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)
- Arrange for electrocardiogram (ECG), only if the patient has any of the following:

- History of congenital heart disease or previous cardiac surgery 0
- 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: (Specialist Clinician)

- 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

### **Ongoing monitoring (ADHD):**

Ensure the patient receives a review at least annually with a healthcare professional with training and expertise in managing ADHD. This may be in primary or secondary care, depending on local arrangements, and should include a review of ADHD medication, including patient preferences, benefits, adverse effects, and ongoing clinical need. Consider trial periods of stopping medication or reducing the dose when assessment of the overall balance of benefits and harms suggests this may be appropriate. If continuing medication, document the reasons why.

Review outcomes should be communicated to the primary care prescriber in writing, with any urgent changes also communicated by telephone.

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

Back to top

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

Monitoring and actions	Frequency	
Maintenance:		
<ul> <li>Weight</li> <li>Blood pressure and heart rate, and assessment for cardiovascular signs or symptoms</li> <li>Height and weight using centiles and appetite</li> <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> <li>Assessment for any indication of abuse, misuse, or diversion</li> <li>In people of child-bearing potential, assess whether there is a risk of pregnancy. Consider pregnancy testing where appropriate</li> </ul>	Every 6 months Specialist Clinician until Primary Care Prescriber has agreed to take on prescribing. At this point the GP is requested to carry out the 6-monthly review and the specialist clinician will carry out the annual review  Annually Specialist Clinician, with bloods arranged through primary care	
<ul> <li>Review of ADHD medication, including preferences of the patient, their family or carer, benefits, adverse effects, and ongoing clinical need. Consider trial period off medication</li> </ul>	anough phinary care	
If dose change when on maintenance:     • Pulse, BP     • Weight, Height, (use centiles), Appetite     • Psychiatric symptoms	Specialist clinician	

(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

Back to top

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

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

Result		Action for primary care	
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance			
Cardiovascular	Symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea or other signs or symptoms suggestive of cardiac disease	Refer for urgent specialist cardiac evaluation	
	Resting tachycardia >120 beats per minute, arrhythmia or systolic blood pressure greater than the 95th percentile (or a clinically significant increase) measured on 2 occasions	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 refer to specialist for further advice	
Weight or BMI	outside healthy range or falling off centiles, anorexia or weight loss	<ul> <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> </ul>	

		Discuss with specialist if difficulty persists; dose reduction, treatment break, or change of medication may be 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
Psychiatric disorders	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
Nervous system disorders	New or worsening seizures	Stop lisdexamfetamine and discuss with specialist. Discontinuation may be indicated
	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
	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

# 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/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
- 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, 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 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:

- NHS attention deficit hyperactivity disorder. https://www.nhs.uk/conditions/attentiondeficit-hyperactivity-disorder-adhd/
- Choice and medication
  - o https://www.choiceandmedication.org/sabp/condition/attention-deficithyperactivity-disorder/ https://www.choiceandmedication.org/sabp/generate/pilllisdexamfetamineparen tuk.pdf

# 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 on the principles of medicines use in breast feeding, and sources of information is available from: Advising on medicines during breastfeeding - SPS -Specialist Pharmacy Service – The first stop for professional medicines advice

#### Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified.

# 13. Specialist contact information

Back to top

Email address: neurodevworkrequests@sabp.nhs.uk (Response within 72 hours)

To contact the specialist on the following telephone number if urgent advice needed: 01372 216555

Alternative contacts

Specialist Pharmacy Services Medicines Advice - on 0300 770 8564 or via email at <a href="mailto:asksps.nhs@sps.direct">asksps.nhs@sps.direct</a> (Service operates Monday to Friday 9am-5pm)

SABP Pharmacy Service - pharmacy@sabp.nhs.uk, 01483 443717

Out of hours contact details: No SABP service providing this level of care for ADHD. Consider emergency services

Families and carers can contact the specialist service on the following telephone number 01372 216555 (Monday - Friday, 9-12.30pm) or email neurodevworkrequests@sabp.nhs.uk for urgent advice and guidance related to their ADHD treatment.

A free out-of-hours phone line - 0300 222 5755 (5pm -11pm, 365 days a year) provides advice to parents and carers who are struggling with behaviours or difficulties which could be related to neurodevelopmental need, such as autism or ADHD.

In addition, advice for the young person and their family or carer can be accessed through:

https://www.mindworks-surrey.org/our-services/access-and-advice

If a patient requires additional support, which is not related to their ADHD treatment, then referral via a health, education or social care practitioner, would normally be required.

### 14. Additional information

Back to top

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.

All involved healthcare professionals should ensure a prompt transfer of care that includes effective information sharing and continued access to the medicines by the patient during the transition.

15. References 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. Lisdexamfetamine, last updated 4th September 2020. Accessed via https://bnf.nice.org.uk/drugs/lisdexamfetamine-mesilate/ on 04/05/2021
- Lisdexamfetamine dimesylate 20 mg hard capsules (Elvanse®). Date of revision of the text: 11/01/21. Accessed via https://www.medicines.org.uk/emc/search?q=lisdexamfetamine on 13/05/21
- Lisdexamfetamine dimesylate 30 mg hard capsules (Elvanse® Adult). Date of revision of the text: 11/01/21. Accessed via https://www.medicines.org.uk/emc/product/6828/smpc on 13/05/21
- The Renal Association. CKD Stages. Accessed via <a href="https://renal.org/health-">https://renal.org/health-</a> professionals/information-resources/uk-eckd-guide/ckd-stages on 13/05/21 [Not currently available]
- NICE. NG46: Controlled drugs: safe use and management. April 2016. Accessed via https://www.nice.org.uk/guidance/ng46/ on 05/05/2021
- Gov.uk: Drugs and driving: the lawGov.uk. Drugs and driving: the law. Accessed via https://www.gov.uk/drug-driving-law on 13/05/21
- 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 13/05/2021 Not currently available
- NICE Clinical Knowledge Summaries. Attention deficit hyperactivity disorder: last revised January 2021. Accessed via https://cks.nice.org.uk/topics/attention-deficit-hyperactivitydisorder/prescribing-information/amfetamines/ on 13/05/21

# 16. Other relevant national guidance

Back to top

- Shared Care for Medicines Guidance A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/ [Not currently available]
- NHSE guidance Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-betweenprimary-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/ethicalguidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-anddevices/shared-care

NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/

# 17. Local arrangements for referral

Back to top

Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

See section 13 for details of advice relating to management of ADHD for an individual continuing with shared care

Where a second mental health or neurodevelopmental condition has emerged:

- 1. and the primary need remains related to their ADHD, and the person may need to be transferred to cohort 3 with the cessation of shared care - access SABP care via email neurodevworkrequests@sabp.nhs.uk
- 2. and the primary need is NOT related to their ADHD (ie, concerns regarding emotional wellbeing or other mental health needs), please refer as usual to Access and Advice (AAT) which is available from 8am to 8pm, Monday to Friday and 9am to 12pm, Saturday. Tel.: 0300 222 5755

APC board date: Last updated:

# **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.

# **Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)**

### **Primary Care Prescriber Response**

Dear	[insert Doctor's name]
Patient	[insert Patient's name]
NHS Number	[insert NHS Number]

Identifier [insert patient's date of birth and/oraddress]

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from [insert date] and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: _	ate:
, -	

Primary Care Prescriber address/practice stamp

# **Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)**

Re:

**Patient** [insert Patient's name] NHS Number [insert NHS Number]

Identifier [insert patient's date of birth and/oraddress]

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS [insert CCG name], in conjunction with local acute trusts have classified [insert medicine name]as a Shared Care drug and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which applies
1.	The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care	
	As the patient's primary care prescriber, I do not feel clinically confident to manage this patient's condition because <i>[insert reason]</i> . I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice.	
	I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.	
2.	The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement	
	As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time.	
	Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you	

# A minimum duration of supply by the initiating clinician As the patient has not had the minimum supply of medication to be provided by the initiating specialist, I am unable to take clinical responsibility for prescribing this medication at this time. Therefore, can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you. Initiation and optimisation by the initiating specialist As the patient has not been optimised on this medication, I am unable to take clinical responsibility for prescribing this medication at this time. Therefore, can you please contact the patient as soon as possible to provide them with the medication that you have recommended. Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you. 5. **Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed. For this reason, I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible to provide them with the medication that you have recommended. Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you. Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and

the dissemination of sufficient, up-to-date information to individual GPs." In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely	
Primary Care Prescriber signature: _ Date:	

**Primary Care Prescriber address/practice stamp** 

### Appendix 4

NHS Surrey Heartlands has worked with its Mental Health provider (Surrey and Borders Partnership NHS Foundation Trust [SABP]) to define cohorts of children who have been diagnosed with ADHD to support effective management across the primary care / specialist service interface.

These cohorts have been defined as follows:

Cohort 1	<ul> <li>Children and young people who are stable:</li> <li>Fully stabilised dose (i.e., titrated dose of medication which has not been changed in the recent six-month period)</li> <li>uncomplicated by co-morbidities (i.e., currently not receiving specialist treatment for other mental health or neurodevelopmental conditions)</li> <li>suitable for ongoing treatment and six-monthly reviews in primary care</li> </ul>
Cohort 2	Children and young people who have ADHD and are currently receiving specialist treatment for other mental health or neurological comorbidities. However, are easily stabilised with small changes but are perhaps seen more frequently by specialist services. These CYPs may be suitable for shared care.
Cohort 3	Children who have <b>co-morbidities and/or have complex needs due to risk</b> (mental health / safeguarding / physical health), may be on other forms of medication and doses of medications are frequently changed hence need regular review by the specialist service. These CYPs are not suitable for shared care and prescribing responsibility should stay within the specialist service.