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Surrey Downs, Guildford and Waverley, North West Surrey and Surrey Heath CCGs

SHARED CARE Guideline – Amber Traffic Light Classification		
Name of medicine	Lisdexamfetamine	
Indication (including whether for adults and/or children)	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Childhood 6-17 years. NOTE: to be used by practices participating in the Locally Commissioned Service - 12 monthly review monitoring for CNS stimulants, atomoxetine, guanfacine and melatonin (Circadin®)	
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The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.
This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications.
The SCG must be used in conjunction with the PCN agreed core roles and responsibilities stated in annex A.
An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Roles and Responsibilities

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Consultant / Specialist responsibilities
1 Ensure baseline monitoring of height, weight, BP, pulse rate have been performed plus any additional relevant investigations such as ECG in case of family history of arrhythmia or sudden death or heart disease.
2 Set the review interval and criteria. The Specialist must ensure contact four weeks after initiation of treatment to assess if being effective. An appointment should be arranged three months after initiation of treatment to undertake necessary monitoring (see point 3 below). Once a child's treatment is stabilised face to face 12 monthly reviews are provided by the Specialist. Specialist ADHD nurses, junior doctors and other staff are closely involved with the monitoring of the patients. When junior / middle grade doctors are helping the Specialists in the clinic, changes should be made after discussion with the Specialist only, and should be clearly stated in a letter to the GP.
3 Undertake any necessary monitoring at clinic appointments (initially three monthly, then 12 monthly in the long term): blood pressure, pulse rate, weight and height (including centiles). Unless the child has symptoms routine monitoring of full and differential blood counts are not

	carried out.
4	Supply the medication until the dose is stabilised. Prescribing may be transferred to the GP under shared care once the patient is stabilised on medication. The GP will not be asked to prescribe the drug outside its licensed indications
5	Request agreement of shared care with primary care prescriber: a detailed clinic letter highlighting relevant patient information should be sent to the GP requesting shared care including the date of the next follow up review.
6	Shared care should only be requested if the patient is stable. Once shared care is agreed advise the patient that their next 6 monthly review will take place with their GP
7	To collate (including on centile charts) and review the physical medication monitoring results received from the patient's GP practice by email every 12 months (received 6 months after the specialist review detailed in point 3) and advise the GP of any required actions. The bottom section on the results form received from the patient's GP practice should be completed and the form emailed back to the practice after each GP physical medication review.
8	Maintain good communication with the GP and provide urgent advice on the following telephone number -**:** 0300 2225755. A written letter should be sent to the GP after each clinic visit notifying the GP of changes in the medication regime, adverse effects and results of the patient's routine monitoring. The GP must be notified of non-attendance at clinic. (**NOTE**: patients that regularly do not attend their 6 monthly reviews are not appropriate for shared care)
9	Keep the GP fully informed about the patient's condition and medication. The specialist will be available to answer queries from the GP and carers during the treatment period.
10	Stop or modify the dosage as appropriate
11	Advise the GP when the treatment is being discontinued. The specialist will provide necessary supervision and support during the drug discontinuation phase.
12	Liaison with other members of the multidisciplinary team responsible for the child's development and education. The parents and class teachers should be given information about methylphenidate in particular the monitoring and side effects.
13	Evaluate adverse drug reactions reported by the GP or carer.
14	To refer patients who develop symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea, or other symptoms suggestive of heart disease for prompt specialist cardiac evaluation.
15	The appropriateness of medication into adulthood should be carefully reviewed. If the drug is to be continued beyond the age of 18, the Specialist will seek to make appropriate arrangements.
16	Continue supply of medication for children under six years.

	Primary Care Prescriber
1	Monitor patient's overall health and wellbeing
2	Continued prescription of treatment, once patient is stabilised on medication and shared care is agreed, at the appropriate intervals given the nature of the drug and the family involved. As it is not necessary for a doctor to see the child more than every 3-6 months, unless there are specific indications, repeat prescriptions can be issued without necessarily seeing the child on each occasion.
3	To check that the patient is attending their 12 monthly specialist ADHD clinics and thus continued prescription is required.
4	To carry out a physical medication review monitoring the following on a 12 monthly basis (the patient will be reviewed 6 monthly in line with the product license, with reviews alternating between GP 12 monthly review and specialist 12 monthly review): ○ Height weight and appetite ○ Blood pressure and pulse

Results of the above tests should be communicated to the specialist service for reviewing and collating in patient records: to support this a template is available attached as Annex B. After reviewing the monitoring results received the specialist will advise the GP of any required actions.

5 To refer patients who develop symptoms such as palpitations, exertional chest pain, unexplained syncope, dyspnoea, or other symptoms suggestive of heart disease for prompt specialist cardiac evaluation.

6 The practice should communicate to the specialist after every physical medication review. This will enable the specialist to know if the patient is not attending GP follow up which may highlight a safeguarding concern for example.

7. To inform the consultant via the fax number or email address below if the patient does not attend their 12 monthly physical medication review for advice in particular in relation to appropriate continued prescription.

CCG	CAMHS	Contact number for GPs for advice and guidance	CAMHS Team Fax Number	CAMHS Team email
NWS CCG	NW CAMHS (Ashford + St Peters)	0300 2225755	Ashford 01784 884359 St Peters 01932 722563	RXX.SABPCAMHSNW@nhs.net
SD	NE CAMHS (Epsom + Dorking)	0300 2225755	01372 204125	RXX.SABPCAMHSNE@nhs.net
ES	SE CAMHS (Redhill + Tandridge)	0300 2225755	01372 217144	RXX.SABPCAMHSSE@nhs.net
GW	SW CAMHS (Guildford and Surrey Heath)	0300 2225755	01483 443770	RXX.SABPCAMHSSW@nhs.net
SH	SW CAMHS (Guildford and Surrey Heath)	0300 2225755	01372 217 149	RXX.SABPCAMHSSW@nhs.net

8. As this is a Controlled Drug, if the GP has information about previous misuse of drugs by family members, they should alert the relevant specialist service to this.

Patient, relatives & carers

1 To attend 6 monthly appointments (both with your GP and the specialist service). Non-attendance of appointments may result in treatment being stopped

2 To contact the specialist team for information and advice if required, during the treatment period.

Key information on the medicine

Background to disease and use of medicines for the given indication

Attention Deficit Hyperactivity Disorder (ADHD) is one of the most commonly diagnosed behavioural disorders of childhood, affecting 1-5% of school age children. Its basic symptoms include developmentally inappropriate levels of attention, concentration, activity, distractibility and impulsivity. It causes problems at home, in school and with peer relationships and may have long term adverse effects on self-confidence, academic performance, vocational success and social development.

- It can be divided into three types, depending on whether inattention or hyperactivity is the predominant presentation
- It must have been present for at least six months and be maladaptive and inconsistent for the age of the child (although in the case of developmental delay the developmental age should be taken into account).
- There must be clear evidence of impairment in social and / or academic functioning
- Some impairment must be present in at least two settings
- The symptoms must be present in at least two settings
- The symptoms must be present before the age of seven
- The symptoms must not be accountable for by any other type of mental disorder or illness although they may occur in conjunction with some development disorders.

Its consequences are low self-esteem, emotional and social problems which may lead to further problems with drug abuse etc in the longer term. These children's academic achievements are often very low consequently often leading to employment problems.

Where drug treatment is considered appropriate, methylphenidate, atomoxetine, lisdexamfetamine and dexamfetamine are recommended, within their licensed indications, as options for the management of ADHD in children. The decision regarding which product to use should be based on the following:

- The presence of co-morbid conditions (for example, tics disorders, Tourette's syndrome, epilepsy)
- The different adverse effects of the drugs
- Specific issues regarding compliance identified for the individual child, for example problems created by the need to administer a mid-day treatment dose at school
- The potential for drug diversion (where the medication is forwarded on to others for non-prescription uses) and/or misuse
- The preferences of the child and/or his or her parent or guardian.

If there is a choice of one or more appropriate drugs, the product with the lowest cost (taking into account the cost per dose and number of daily doses) should be prescribed.

Diagnosis

Should be made by a child / adolescent psychiatrist or paediatrician with a special interest in ADHD, involving the child, its carers and school. A multidisciplinary assessment including educational and clinical psychologists, social workers etc may be necessary in individual cases. **Almost 50% of children who have ADHD may have other co-morbid conditions which**

include autistic spectrum/Asperger's syndrome, dyslexia, dyspraxia and oppositional-defiant difficulties. Recognising these conditions is important to ensure comprehensive planning is made.

Technology

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

- Lisdexamfetamine is a prodrug – the dexamfetamine is complexed with the amino acid lysine and in this form is inactive. It is broken down in red blood cells to gradually release dexamfetamine.
- Lisdexamfetamine is considered to have less potential for abuse than dexamfetamine.
- Lisdexamfetamine is a controlled drug and is subject to full controlled drug requirements relating to prescriptions and safe custody.

Dose and licensing

NICE guidelines on the diagnosis and management of ADHD advise to consider switching to lisdexamfetamine for 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.

Lisdexamfetamine is not licensed for children less than 6 years of age but may be so used under certain circumstances by the specialist.

Lisdexamfetamine dimesylate is a pharmacologically inactive prodrug. After oral administration, lisdexamfetamine dimesylate is rapidly absorbed from the gastrointestinal tract and hydrolysed primarily by red blood cells to dexamfetamine.

DOSE: The starting dose for all patients is 30mg once daily in the morning. This may be increased at approximately weekly intervals by 20mg increments, to a maximum of 70mg once daily. The lowest effective dose should be administered.

- Lisdexamfetamine dimesylate may be taken with or without food. The capsules should be swallowed whole or opened, the contents dispersed in a glass of water (stir until completely dispersed) and the resulting solution swallowed immediately (a film of inactive ingredients may remain in the glass).

- Afternoon doses should be avoided (risk of insomnia). If there is a missed morning dose, wait until the following morning before administering the next dose.

- Treatment should be stopped if the symptoms do not improve after 1 month at an appropriate dose. Reduce the dosage if paradoxical aggravation of symptoms/other intolerable adverse events emerge.

Monitoring

Monitoring requirements including frequency and appropriate dose adjustments	Responsible clinician
Pre-treatment: • Pulse, blood pressure, weight, height, psychiatric symptoms,	*Specialist Clinician*

ECG in case of family history of CVD, arrhythmia or sudden death. • Weight and height should be plotted on an appropriate growth chart.	
Initiation: **At three months after initiation:** • Height weight and appetite (including centiles) • Blood pressure and pulse • Psychiatric symptoms • Monitor for appearance or worsening of anxiety depression or tics	*Specialist Clinician*
Maintenance: The patient will be reviewed 6 monthly in line with the product license, with reviews alternating between GP 12 monthly review and specialist 12 monthly review: • Height and weight (including centiles) • Blood pressure and pulse • Psychiatric symptoms • Monitor for appearance or worsening of anxiety depression or tics	*Specialist Clinician until Primary Care Prescriber has agreed to take on prescribing.*
If dose change when on maintenance: • Height and weight (including centiles) • Blood pressure and pulse • Psychiatric symptoms • Monitor for appearance or worsening of anxiety depression or tics	*Specialist Clinician until Primary Care Prescriber has agreed to take on prescribing.*

Test	Abnormal Result	Action if Abnormal Result
Family or personal cardiac history at baseline	**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 suggesting cardiac origin** **Signs of heart failure** **A murmur heard on cardiac examination** **Blood pressure that is classified as hypertensive for adults**	**Refer for cardiology opinion before starting treatment**
Blood pressure at baseline	**consistently above the 95th centile for age and height for children and young people**	**Refer to a paediatric hypertension specialist**

Any cardiovascular parameters	**Outside normal range for child of that age**	**Refer for cardiac evaluation**
Growth velocity (height or weight)	**Outside normal range for child of that age**	**consideration should be given to dose reduction or interrupting therapy in children and adolescents who are not growing or gaining weight satisfactorily**

Support and Advice for the Primary Care

CAMHS OneStop **0300 2225755**

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

References:

1. NICE guideline 87 March 2018: Attention deficit hyperactivity disorder, Diagnosis and management.
2. Summary of Product Characteristics, Elvanse® –www.medicines.org.uk (accessed 30 July 2018).

Other references used:

- SIGN clinical guideline 112 October 2009: Management of attention deficit and hyperkinetic disorders in children and young people.
- Ashford and St Peter's Hospital NHS Trust Shared Care Protocol for the use of Atomoxetine (Strattera®) in Attention Deficit Hyperactivity Disorder in Childhood, August 2004.
- Blackwater valley and Hart, & North Hampshire Primary Care Trusts Treatment Plan and Shared Care Agreement Methylphenidate (Ritalin®, Equasym®, Concerta XL®), Atomoxetine (Strattera®) and Dexamphetamine (Dexedrine®) for attention deficit hyperactivity disorder (ADHD) in children and adolescents Dec 2005.

Annex A: PCN agreed core roles and responsibilities for the shared care of medicines

Patients
To get the most out of your treatment it's important that you work together with your specialist. You must follow these guidelines to ensure your own safety, health and wellbeing. You should be able to decline shared care If after due consideration of the available options you decide it is not in your best interests. • You must make sure that you understand about your treatment • If you do not understand ask for more information from the person prescribing the medicine • Read the Patient Information Leaflet included with your medication. It will provide you with information about your medication • You must raise concerns about your treatment with the person prescribing the medicine • Talk to the specialist and come to an agreement of how the treatment should be provided to you • Give permission to have aspects of your care communicated to healthcare providers • Ensure that you are provided with contact details for support and help if required; both in and out of hours. • You must attend all appointments • You must keep a written list of all of the medicines you are taking • You must keep lists of any additional vitamins, minerals, or other dietary supplements • You must bring these lists with you each time you visit a healthcare provider or are admitted to a hospital • You must carry these lists on you in case of an emergency • You must not let anyone else take your medication. It is your responsibility to follow these guidelines. The guidelines are here for your safety, health and wellbeing. If you would like more information on your rights, roles and responsibilities in your healthcare please ask a NHS professional for information on the NHS constitution or visit, www.gov.uk/government/publications/the-nhs-constitution-for-england
Relatives and Carers
As a carer or relative (where it is not possible for the patient to make a decision about future treatment e.g. mental capacity, where possible you should be included in discussions about shared care. • To support the patient in fulfilling their roles and responsibilities as outlined above.
Consultant/ Specialist
Good Prescribing Guidelines • Be aware that if you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required (Ref GMC). • Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required. • Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the PCN with input from specialists and Primary Care Prescribers, and, for individual patients, the patient's Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care. • Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the patient's CCG • Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with your Formulary Pharmacist who will facilitate an update via the PCN

Before initiating treatment

- Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions.
- Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences
- Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment.
- Undertake baseline monitoring and assessment.

Initiating and continuing treatment in secondary care

- Prescribe initial treatment and provide any associated training and counselling required.
- Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record
- Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable or predictable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
- At any stage of treatment, advising Primary Care Prescriber of concerns regarding monitoring or potential adverse effects of treatment

Transfer of care to Primary Care prescriber

- Liaise with the primary care prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Only advise the patient that shared care will take place, and prescribing will be transferred, once the primary care prescriber has agreed to share responsibility of the patient care, and that this has been confirmed in writing.
- If the primary care prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

Post transfer of care

- Follow up and monitor the patient at appropriate intervals.
- Advise Primary Care Prescriber if treatment dose changes or treatment is discontinued
- Inform Primary Care Prescriber if patient does not attend planned follow-up

Primary Care Prescriber

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the PCN as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
- It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).
- Keep yourself informed about all the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely

manner.

- Continue prescribing medicine at the dose recommended and undertake monitoring requirements
- Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline
- Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
- Inform the Consultant or specialist of any issues that may arise
- Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g. ensuring the patient record is correct in the event of a patient moving practice).

All

- Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation PCN representative who will facilitate an update via the PCN.

Annex B: Shared care agreement notification form for medicines and indications approved as amber on the Surrey PAD or Crawley, Horsham and Mid-Sussex net formulary.

For the attention of the Practice Manager

FAX – Confirm you have the correct Safe Haven Fax Number before sending
E-mail – Confirm both sender and recipient e-mail addresses are nhs.net before sending

To:	[Recipient Name]	Fax:	[fax number]
From:	[Your Name]	Date:	[Click to select date]
Re:	[Subject]	Pages:	[number of pages]
cc:	[Name]		

[Notes]

Name of medicine	Lisdexamfetamine
Indication	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Childhood 6-17 years. NOTE: to be used by practices participating in the Locally Commissioned Service - 12 monthly review monitoring for CNS stimulants, atomoxetine, guanfacine and melatonin (Circadin®)

Person removing form from fax machine	
Relevant patients GP available to action within 5 days (if not Trust needs to be informed on day of receipt of request)	Yes/ No
If GP is NOT available within 5 days, please communicate to the requesting specialist the date when the GP will be available	

Hospital/ Patient information		**Practice information**	
Consultant Making Request		GP Name:	
Consultant Speciality Details:		Practice:	
Patient Name:		I agree to undertake shared care:	
Patient NHS Number:		I do not agree to undertake shared care:	
Patient Hospital Number:		If NOT please give reasons:	
Patient DOB:		Signed:	
Drug Name/ Dose:		Date:	
Next Prescription Due:		Please return form to:	Specialist safe haven fax number
Blood pressure:		Date:	
Pulse		Date:	

Height		Date:	
Weight		Date:	
BMI		Date:	
Discharge letter written and sent:			
Please refer to the Surrey PAD or Crawley, Horsham and Mid-Sussex net formulary for relevant shared care documents			

ADHD Shared Care Protocol Follow Up Sheet – 12 monthly review monitoring

Patient name/ Date of Birth **NHS Number/ Hospital number**	**GP PRACTICE STAMP**

Height (cm)	**Weight (kg)**	**BMI**	**Pulse**	**BP**
Previous: ______________ Date: ______________ Current: ______________ Date: ______________	Previous: ______________ Date: ______________ Current: ______________ Date: ______________	Previous: ______________ Date: ______________ Current: ______________ Date: ______________	Previous: ______________ Date: ______________ Current: ______________ Date: ______________	Previous: ______________ Date: ______________ Current: ______________ Date: ______________

Medication (name/s and current dosage)	
Does this child require an early review at the CAMHS team(Planned review at CAMHS 12 monthly)	Yes/No If Yes- Why?

Please email or fax back when completed to the CAMHS team:

CCG	CAMHS	Contact number for GPs for advice and guidance	CAMHS Team Fax Number	CAMHS Team email
NWS CCG	NW CAMHS (Ashford + St Peters)	0300 2225755	Ashford 01784 884359 St Peters 01932 722563	RXX.SABPCAMHSNW@nhs.net
SD	NE CAMHS (Epsom + Dorking)	0300 2225755	01372 204125	RXX.SABPCAMHSNE@nhs.net
ES	SE CAMHS (Redhill + Tandridge)	0300 2225755	01372 217144	RXX.SABPCAMHSSE@nhs.net
GW	SW CAMHS (Guildford and Surrey Heath)	0300 2225755	01483 443770	RXX.SABPCAMHSSW@nhs.net
SH	SW CAMHS (Guildford and Surrey Heath)	0300 2225755	01372 217 149	RXX.SABPCAMHSSW@nhs.net

This section is to be completed by the **CAMHS Team**:

Date shared care information received by SABP: _____

Date of next appointment for patient at SABP: _____

Any actions required to be undertaken by GP based on above results:

Once above details have been completed **please email / fax back** to practice (see details in GP practice stamp box for fax or return to email form received on)