SHARED CARE GUIDELINE

Lisdexamfetamine in the treatment of Attention Deficit Hyperactivity Disorder in Children, Young People and Adults

Implementation Date: August 2016
Review Date: August 2018
This guidance has been prepared and approved for use within, Sunderland in consultation within the CCG, Secondary Care Trusts and Local Medical Committees.
The guideline sets out the details of the transfer of prescribing and respective responsibilities of GPs and specialist services within shared care prescribing arrangements. It is intended to provide sufficient information to allow GPs to prescribe these treatments within a shared care setting

Approved by:

Committee	Date
Sunderland Joint Formulary Committee	July 2016
Sunderland Medicines Optimisation Committee	August 2016

Lisdexamfetamine dimesylate is a pharmacologically inactive prodrug. It is rapidly absorbed through the GI tract and enzymatically hydrolysed to the active compound dexamfetamine. This requirement for enzymatic hydrolysis gives lisdexamfetamine a lower abuse potential than dexamfetamine. Medium peak plasma levels last for 3-6 hours and studies have demonstrated an extended of activity in children of 13hrs, allowing once daily dosing.
Licensed (amber) Indications: for use in children aged over 6 years and adults for the treatment of ADHD.
Lisdexamfetamine is a schedule 2 controlled drug and is therefore subject to normal controlled drug regulations.

SHARED CARE GUIDELINE			
Non-proprietary name	Lisdexamfetamine		
Availability	**For children and young people** Elvanse® 20mg, 30mg, 40mg, 50mg, 60mg and 70mg capsules (hard) **For adults** Elvanse Adult® 30mg, 50mg, and 70mg capsules (hard)	BNF class	4.4
Indication	Lisdexamfetamine is a CNS stimulant drug used in the treatment of Attention Deficit Hyperactivity Disorder (ADHD). It should only be initiated following assessment and diagnosis by a specialist with expertise in ADHD, as part of a comprehensive treatment plan, in children aged 6 years and over, for second line use where a trial of previous treatments has been inadequate or not tolerated.		
Dosage and Administration	**See BNF, BNFC and NICE ADHD CG 72 Clinical Guideline 2008** **Children + Young People** -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 dose may be increased by 10 or 20 mg increments, at approximately weekly intervals. **Adults** - the starting dose is lisdexamfetamine (Elvanse Adult ®) 30mg taken once daily in the morning increased in 20mg increments at approximately weekly intervals In patients with severe renal insufficiency (GFR 15 to <30 mL/min/1.73 m2 or CrCl <30 mL/min) the maximum dose should not exceed 50 mg/day. Further dosage reduction should be considered in patients undergoing dialysis **The maximum recommended dose is 70 mg/day; higher doses have not been studied**. Lisdexamfetamine may be taken with or without food. It 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. If the contents include any compacted		

	powder, a spoon may be used to break apart the powder in the soft food or liquid. The contents should be stirred until completely dispersed. The patient should consume the entire mixture of soft food or liquid immediately; it should not be stored. The active ingredient dissolves completely once dispersed; however, a film containing the inactive ingredients may remain in the glass or container once the mixture is consumed. The patient should not take anything less than one capsule per day and a single capsule should not be divided. In the event of a missed dose, Lisdexamfetamine dosing can resume the next day. Afternoon doses should be avoided because of the potential for insomnia
Eligibility criteria for shared care	Children over 6 years of age and adults who have been assessed by a specialist and have a diagnosis of ADHD
Excluded patients	Children under 6 years of age
Initiation	The patient is initiated on treatment, titrated to a therapeutic dose then supplied with a further month's treatment by the specialist to give time for shared care to be arranged. In some circumstances it may be more appropriate for the GP to prescribe lisdexamfetamine on the advice of a specialist during the initiation and titration phase. This must be done on a case by case basis by prior arrangement and all the necessary information for the GP to do this safely must be provided by the specialist. Both the Specialist and the GP must agree to the shared care arrangement.
Specialist Responsibilities	**Pre-Treatment** - Diagnose the condition and assess suitability for treatment with lisdexamfetamine (as per the pre-drug assessment in NICE guidance) Review the patient's relevant medical history and physical examination including: • history of exercise syncope or undue breathlessness • family history of serious cardiac disease • examination of the cardiovascular system. Usually this information will be available to the specialist, if not; the specialist will work in collaboration with the GP. Only prescribe or ask the GP to prescribe if this information is available. **Request an ECG if there is a past medical or family history of serious cardiac disease or abnormal findings on cardiac examination - symptoms suggestive of heart disease should prompt specialist cardiac evaluation** Routine blood tests are not recommended unless there is a clinically indicated. Carry out a pre-drug treatment assessment, including • a full mental health and social assessment**,** • risk assessment for substance misuse and drug diversion. • baseline weight and height, heart rate and blood pressure • request GP to undertake any necessary further investigations. Provide patient/carer with relevant information on use, side effects and need for monitoring of medication - document this is in the medical notes. **Contact the GP to seek formal agreement for the shared care.** Provide the GP with relevant information including: • Treatment to be undertaken by GP (dose, any dosage titrations etc) • System of monitoring and recording of progress and side effects **Monitoring** - condition: Assess response to treatment and the need to continue therapy by reviewing the patient at regularly as per specialist review schedule. Monitoring side-effects: • Appetite, height (not applicable for adults) & weight: Every 6 months • BP & pulse: Approximately every 3 months as per specialist's review schedule and with each dose change. Symptoms suggestive of heart disease should prompt specialist cardiac evaluation • Assess for: development of tics, psychotic symptoms, anxiety, or seizures

	Treatment must be stopped if the symptoms do not improve after appropriate dosage adjustment over a 1-month period. If paradoxical aggravation of symptoms or other intolerable adverse events occur, the dosage should be reduced or discontinued. Review treatment regularly, sending a written summary to the GP at each review. Provide any other advice or information for the GP if required Ensure changes to treatment are communicated in writing to the GP as soon as possible. Supervise treatment discontinuation, or onward referral to adult service if appropriate. Liaise with the GP if any other additional tests/monitoring is required. Monitor and liaise with the GP regarding any adverse effects, which occur during treatment, including reporting of all serious adverse drug reactions to the MHRA. Notify the GP of failed attendance
GP Responsibilities	• Prescribe lisdexamfetamine following recommendations of the specialist. It is strongly recommended that prescriptions are issued for maximum treatment duration of **one month**, in line with good practice guidance for controlled drug • Provide the specialist with relevant medical history and background information. • Notify the specialist of any family/social circumstances which may preclude treatment with lisdexamfetamine (including current/past use of illicit drugs) • If the GP becomes aware that the patient has started misusing substances such as cocaine, heroin or amphetamines, care should be transferred back to the specialist. • To contact the specialist if concerned about any aspects of the patient's treatment. • Report significant deviations from the prescribing pattern to the specialist • Monitor and record the therapy in accordance with written directions of specialist • For adults - review the patient at 6 months (in between their specialist annual review) to monitor the weight, heart rate and BP as per specialist recommendations. • Report any adverse events to the specialist, and the usual bodies. (Eg MHRA).
Adverse Effects, Precautions and Contraindications	Glaucoma Marked anxiety, agitation, tension or psychosis Hyperthyroidism Current / recent (within 14 days) treatment with MAOIs *Some Cardiovascular diseases *Motor tics, or family history of Tourette's syndrome *Although these last two are listed as contraindications, in some circumstances, lisdexamfetamine can be used with caution and careful monitoring by the specialist. Use with caution in epilepsy. If seizure frequency increases, the specialist should discontinue lisdexamfetamine. Dizziness, nervousness, drowsiness and headaches are commonly experienced upon initiation of therapy. Loss of appetite (some weight loss may occur) and insomnia may also occur. These effects are often mild and transient and may be controlled by a reduction in dose. Other adverse effects include: abdominal pain, nausea and vomiting (can be alleviated with concomitant food intake), dry mouth, emotional lability, temporary growth retardation, changes in blood pressure, tachycardia, palpitations, skin rash, itching or bruising
Common Drug Interactions	<u>Monoamine oxidase inhibitors</u> Amfetamine should not be administered during or within 14 days following the administration of monoamine oxidase inhibitors (MAOIs) Antihypertensives: Amfetamines may decrease the effectiveness of antihypertensive medications. Amfetamines potentiate the analgesic effect of narcotic analgesics.

Communication/Contact Details	For any queries relating to this patient's treatment with lisdexamfetamine please contact the services named below.

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF

CONTACTS FOR FURTHER INFORMATION

MON – FRI, 09:00 – 17:00:

CYPS

Newcastle and Gateshead	Benton House, Newcastle	0191 2466913
Sunderland and South Tyneside	Monkwearmouth Hospital	0191 5665500
Adult ADHD Team	Keegan Court, Gateshead	0191 2876250

Private and Confidential

Shared Care Request/Confirmation

- Consultant to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist prescriber within 28 day

Specialist Prescriber ……	**Patient details (use hospital label if preferred)**
Department ……	**Name** ……
Hospital ……	**Address** ……
	……
	Postcode ..... **Sex** ……..
	NHS or Hosp. Reg. No. …… **DoB** ……..

Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement

Drug Name **Lisdexamfetamine** **Dose** **Frequency**

Indication

Other Information (if appropriate)

Signed (Specialist Prescriber) **Name (print)** **Date**

To be completed by GP

Please tick one box

I ACCEPT the proposed shared care arrangement for this patient ❑

or

I ACCEPT the proposed shared care arrangement with the caveats below ❑

or

I DO NOT ACCEPT the proposed shared care arrangement for this patient ❑

My caveats / reason(s) for not accepting include:

……..

……..

Signed …… **Name (print)** ..... **Date** ……

(Patients GP)

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP