Effective Shared Care Agreement (ESCA)

Approved for Solihull locality only.

Lisdexamfetamine

ESCA: For the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of lisdexamfetamine in Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with Attention-Deficit/Hyperactivity Disorder (ADHD) are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary
2. Specialist assessment and confirmation of the diagnosis of attention deficit/hyperactivity disorder
3. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
4. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made
5. Do baseline monitoring prior to initiation of this agent: • weight, blood pressure, pulse and essential medical history, cardiovascular examination and ECG where indicated. • full mental health and social assessment, full history and physical examination, family history of cardiac disease and an ECG if there is past medical and/or family history of cardiac or cerebrovascular problems. • risk assessment for substance misuse and potential for drug diversion.
6. Initiate treatment and stabilise dose of lisdexamfetamine
7. Lisdexamfetamine is a Schedule 2 Controlled Drug (CD, therefore should be prescribed in line with the Misuse of Drug Regulations.). Prescription requirements for prescribing CDs should therefore be observed, maximum of 30 day per prescription.
8. Advise the patient on the importance of good adherence with the prescribed medication. Check adherence at each clinic appointment
9. Review the patient's condition and response to treatment every 6 months. Advise patients, families/ carers to report any side effects and/ or concerns. At 6 monthly reviews (unless otherwise indicated): • Monitor efficacy of long term treatment and consider whether benefit can be gained from continued treatment. • Monitor height, weight, appetite, heart rate and BP and any psychiatric symptoms • Request any further investigations that are clinically indicated such as ECG, blood investigations • Assess progress with regards to psychological, behavioural, educational and occupational needs • Assess ongoing need for medication • Assess any side effects • Consider the potential for drug diversion and potential for misuse
10. Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
11. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
12. Advise the GP what to do when defined parameters are altered, and when (if at all) an emergency referral should be made back to the specialist service.
13. Advise GP on the management of side effects and raise awareness at which point these will be reviewed and/ or managed by the specialist.
14. Advise the GP when to stop treatment and on management of discontinuation if necessary.
15. Report serious adverse events to the MHRA via Yellow Card Scheme https://yellowcard.mhra.gov.uk
16. Ensure clear backup arrangements exist for GPs, for advice and support (please complete contact details in appendix 1)

General Practitioner responsibilities
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days
2. Ensure: • Patient/ family are clear who will be responsible for monitoring and what this will entail. • Patient/ family are aware of any significant adverse effects/ events, which should be urgently reported and who these should be reported to. (GP/ specialist)
3. Prescribe lisdexamfetamine at the dose recommended.
4. Lisdexamfetamine is a Schedule 2 Controlled Drug (CD, therefore should be prescribed in line with the Misuse of Drug Regulations.). Prescription requirements for prescribing CDs should therefore be observed, maximum of 30 day per prescription.
5. Adjust the dose as advised by the specialist.
6. In the patient's notes, using the appropriate read code listed below, denote that the patient is receiving treatment under a shared care agreement

GP Prescribing System	Read Code	Description		GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care

7. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist
8. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment
9. Refer back to specialist if condition deteriorates
10. For women of child bearing age, refer prescribing responsibilities back to specialist immediately if patient becomes, or wishes to become, pregnant.
11. Report serious adverse events to specialist and MHRA via the Yellow Card Scheme https://yellowcard.mhra.gov.uk
12. Stop treatment on advice of specialist

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment
2. Attend regularly for required blood tests and annual health checks.
3. Share any concerns in relation to treatment with lisdexamfetamine with the specialist, clinical nurse specialist or GP
4. Report any adverse effects to the specialist or GP whilst taking lisdexamfetamine
5. Attend regular outpatient appointments with the specialist
6. Inform the specialist, clinical nurse specialist or GP if she becomes or wishes to become pregnant.

Please enter Specialist contact details and patient specific information in Appendix 1

SUPPORTING INFORMATION

<table>
<tr><td rowspan="9">Indication</td><td>Lisdexamfetamine
(Elvanse)
20mg, 30mg, 40mg, 50mg, 60mg & 70mg Capsules</td><td>Lisdexamfetamine
(Elvanse Adult)
30mg, 50mg & 70mg Capsules</td></tr>
<tr><td>Indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years and over when response to previous methylphenidate treatment is considered clinically inadequate.</td><td>Indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adults.

Lisdexamfetamine (Elvanse Adult) is not indicated in all adult patients and the decision to use the medicinal product must take into consideration the profile of the patient, including a thorough assessment of the severity and chronicity of the patient's symptoms, the potential for abuse, misuse or diversion and clinical response to any previous pharmacotherapies for the treatment of ADHD</td></tr>
<tr><td colspan="2">Treatment must be under the supervision of a specialist in behavioural disorders. Diagnosis should be based on a complete history and evaluation of the patient according to current DSM criteria or ICD guidelines. Diagnosis cannot be made solely on the presence of one or more symptom.</td></tr>
<tr><td></td><td>In adults, the presence of symptoms of ADHD that were pre-existing in childhood is required and should be confirmed retrospectively (according to the patient's medical record or, if not available, through appropriate and structured instruments or interviews). Based on clinical judgment, patients should have ADHD of at least moderate severity as indicated by at least moderate functional impairment in two or more settings (for example, social, academic, and/or occupational functioning), affecting several aspects of an individual's life.</td></tr>
<tr><td colspan="2">The specific aetiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and specialised psychological, educational, and social resources.</td></tr>
<tr><td colspan="2">A comprehensive treatment programme typically includes psychological, educational and social measures as well as pharmacotherapy and is aimed at stabilising patients with a behavioural syndrome characterised by symptoms which may include chronic history of short attention span, distractibility, emotional lability, impulsivity, moderate to severe hyperactivity.</td></tr>
<tr><td>Minor neurological signs and abnormal EEG. Learning may or may not be impaired.</td><td></td></tr>
<tr><td>Lisdexamfetamine is not indicated in all children with ADHD and the decision to use the drug must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the child's age and potential for abuse, misuse or diversion.
Appropriate educational placement is essential, and psychosocial intervention is generally necessary.
The use of Lisdexamfetamine should always be used in this way according to the licensed indication</td><td></td></tr>
</table>

<table>
<tr><th></th><th colspan="2">Lisdexamfetamine
(Elvanse)
20mg, 30mg, 40mg, 50mg, 60mg & 70mg Capsules</th><th>Lisdexamfetamine
(Elvanse Adult)
30mg, 50mg & 70mg Capsules</th></tr>
<tr><td rowspan="8">Dosage and Administration</td><td colspan="3">Dosage should be individualised according to the therapeutic needs and response of the patient. Careful dose titration is necessary at the start of treatment with Lisdexamfetamine (Elvanse/Elvanse Adult.)</td></tr>
<tr><td colspan="3">The starting dose is 30 mg taken once daily in the morning</td></tr>
<tr><td colspan="2">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.</td><td></td></tr>
<tr><td colspan="2">The dose may be increased by 10 or 20 mg increments, at approximately weekly intervals.</td><td>The dose may be increased by 20 mg increments, at approximately weekly intervals</td></tr>
<tr><td colspan="3">The maximum recommended dose is 70 mg/day; higher doses have not been studied.</td></tr>
<tr><td colspan="3">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.</td></tr>
<tr><td colspan="3">Lisdexamfetamineshould be administered orally at the lowest effective dosage.</td></tr>
<tr><td rowspan="3">Renal Impairment</td><td>Mild</td><td rowspan="2">No data</td></tr>
<tr><td>Moderate</td></tr>
<tr><td>Severe
(GFR 15 to <30 mL/min/1.73 m2 or CrCl <30 mL/min)</td><td>Due to reduced clearance in patients with severe renal insufficiency the maximum dose should not exceed 50 mg/day</td></tr>
<tr><td>Hepatic impairment</td><td colspan="3">No studies have been conducted in patients with hepatic impairment.</td></tr>
<tr><td>Contra-indications / Special precautions</td><td colspan="3"><u>Contraindication</u>
• Hypersensitivity to sympathomimetic amines or any of the excipients listed.
• Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days after MAOI treatment.
• Hyperthyroidism or thyrotoxicosis.
• Agitated states.
• Symptomatic cardiovascular disease.
• Advanced arteriosclerosis.
• Moderate to severe hypertension.
• Glaucoma.

<u>Caution</u>
Abuse and dependence
Stimulants should be prescribed cautiously to patients with a history of substance abuse or dependence.

Cardiovascular adverse events
Sudden death in patients with pre-existing structural cardiac abnormalities or other serious heart problems

Hypertension and other cardiovascular conditions
Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, e.g., those with pre-existing hypertension, heart failure, recent myocardial infarction, or ventricular arrhythmia.

Cardiomyopathy
Cardiomyopathy has been reported with chronic amfetamine use. It has also been reported with Lisdexamfetamine.

Assessing cardiovascular status in patients being treated with stimulant medications
All patients who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease (e.g., electrocardiogram or echocardiogram). Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation.</td></tr>
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Psychiatric adverse events

Pre-existing psychosis

Administration of stimulants may exacerbate symptoms of behaviour disturbance and thought disorder in patients with pre-existing psychotic disorders.

Bipolar illness

Prior to initiating treatment with a stimulant, patients with comorbid depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression.

Emergence of new psychotic or manic symptoms

Treatment emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without prior history of psychotic illness or mania can be caused by stimulants at usual doses. If such symptoms occur, consideration should be given to a possible causal role of the stimulant, and discontinuation of treatment may be appropriate.

Aggression

Patients beginning treatment for ADHD should be monitored for the appearance of or worsening of aggressive behaviour or hostility.

Tics

Clinical evaluation for tics and Tourette's syndrome in children and their families should precede use of stimulant medications.

Long-term suppression of growth (height and weight)

Height, weight, and appetite should be recorded at least 6-monthly.

Seizures

There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizure, in patients with prior EEG abnormalities in absence of seizures, and very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of new onset or worsening seizures, the drug should be discontinued.

Visual disturbance

Difficulties with accommodation and blurring of vision have been reported with stimulant treatment.

Use with other sympathomimetic drugs

Lisdexamfetamine should be used with caution in patients who use other sympathomimetic drugs

Use in adults (For Elvanse Capsules)

Safety and efficacy have not been established for the routine continuation of treatment beyond 18 years of age. If treatment withdrawal has not been successful when an adolescent has reached 18 years of age continued treatment into adulthood may be necessary. The need for further treatment of these adults should be reviewed regularly and undertaken annually.

<table>
<tr><td>Side Effects</td><td>Very common</td><td colspan="3">Decreased appetite, insomnia, headache, weight decreased</td></tr>
<tr><td></td><td>Common</td><td colspan="3">Agitation, anxiety, libido decreased (adults), depression, tic, affect lability, psychomotor hyperactivity, bruxism (adults), dizziness, restlessness, tremor, somnolence, tachycardia, palpitation, dyspnoea, dry mouth, diarrhoea, constipation, upper abdominal pain, nausea, vomiting, hyperhidrosis (adults), rash (children), erectile dysfunction (adults), irritability, fatigue, feeling jittery, pyrexia, blood pressure increased (adults)</td></tr>
<tr><td>Monitoring</td><td>Pre-treatment assessment</td><td colspan="3">Prior to prescribing, it is necessary to conduct a baseline evaluation of a patient's cardiovascular status including blood pressure and heart rate. A comprehensive history should document concomitant medications, past and present co-morbid medical and psychiatric disorders or symptoms, family history of sudden cardiac/unexplained death, and accurate recording of pre-treatment weight</td></tr>
<tr><td></td><td>After commencing treatment</td><td colspan="3">Psychiatric, and cardiovascular status should be continually monitored
Blood pressure and pulse should be recorded at each adjustment of dose and at least every six months.
Development of de novo or worsening of pre-existing psychiatric disorders should be monitored at every adjustment of dose and then at least every six months and at every visit.
Patients should be monitored for the risk of diversion, misuse, and abuse</td></tr>
<tr><td></td><td>Long-term use</td><td colspan="3">Pharmacological treatment of ADHD may be needed for extended periods. The physician who elects to use Elvanse for extended periods (over 12 months) should re-evaluate the usefulness of Elvanse at least yearly, and consider trial periods off medication to assess the patient's functioning without pharmacotherapy, preferably during times of school holidays.</td></tr>
<tr><td></td><td colspan="4">Actions to be taken: (based on existing ADHD ESCA's)</td></tr>
<tr><td></td><td colspan="4"><table>
<tr><th>Parameter</th><th>Frequency of monitoring</th><th>Action</th><th>By Whom</th></tr>
<tr><td>Weight gain</td><td>3 – 6 monthly</td><td>Failure to gain weight appropriately - may require withdrawal.</td><td rowspan="3">Specialist at regular reviews. (If specialist review >6 monthly, GP may be requested to carry out monitoring) For some patients GP may be asked to carry out BP monitoring between appointments.</td></tr>
<tr><td>Blood pressure</td><td>3 – 6 monthly</td><td>Monitor whilst taking medication to ensure within published range for age of child.</td></tr>
<tr><td>Growth Development</td><td>3 – 6 monthly</td><td>If adversely affected consideration should be given to dose reduction or interrupting therapy in those on long-term treatment.</td></tr>
<tr><td>Full Blood Count</td><td>Only if blood dyscrasia suspected</td><td>Manufacturers recommend periodic blood tests to detect haematological abnormality, but we are aware of no evidence for this practice and think that the remote chance of benefit is usually outweighed by the unpleasantness for the child [Ref. Eur Child Adolesc Psychiatry 2004;13 Suppl 1:I7-30.]</td><td>Low threshold for investigation e.g. if recurrent infections or purpuric rash occur</td></tr>
</table></td></tr>
</table>

Drug Interactions (significant interaction as outlined in BNF, please see BNF and SPC for more detail)

Lisdexamfetamine has the following interaction information:

Medication	Severity of interaction	Evidence for interaction	Notes	Action
Apraclonidine	Severe	Theoretical	Lisdexamfetamine is predicted to decrease the effects of apraclonidine. Manufacturer advises avoid.	
Atomoxetine	Severe	Theoretical	Lisdexamfetamine is predicted to increase the risk of side-effects when given with atomoxetine.	
Fluoxetine	Severe	Theoretical	Fluoxetine is predicted to increase the exposure to lisdexamfetamine. Both lisdexamfetamine and fluoxetine can increase the risk of serotonin syndrome.	
Isocarboxazid	Severe	Anecdotal	Isocarboxazid is predicted to increase the risk of a hypertensive crisis when given with lisdexamfetamine. Both lisdexamfetamine and isocarboxazid can increase the risk of serotonin syndrome.	Manufacturer advises avoid and for 14 days after stopping the MAOI.
Moclobemide	Severe	Theoretical	Moclobemide is predicted to increase the risk of a hypertensive crisis when given with lisdexamfetamine. Both lisdexamfetamine and moclobemide can increase the risk of serotonin syndrome.	Manufacturer advises avoid.
Nabilone	Severe	Theoretical	Nabilone is predicted to increase the risk of cardiovascular side-effects when given with lisdexamfetamine.	
Paroxetine	Severe	Theoretical	Paroxetine is predicted to increase the exposure to lisdexamfetamine. Both lisdexamfetamine and paroxetine can increase the risk of serotonin syndrome.	
Phenelzine	Severe	Anecdotal	Phenelzine is predicted to increase the risk of a hypertensive crisis when given with lisdexamfetamine. Both lisdexamfetamine and phenelzine can increase the risk of serotonin syndrome.	Manufacturer advises avoid and for 14 days after stopping the MAOI.
Rasagiline	Severe	Theoretical	Rasagiline is predicted to increase the risk of severe hypertension when given with lisdexamfetamine. Both lisdexamfetamine and rasagiline can increase the risk of serotonin syndrome.	Manufacturer advises avoid.
Ritonavir	Severe	Theoretical	Ritonavir is predicted to increase the exposure to lisdexamfetamine.	
Safinamide	Severe	Theoretical	Safinamide is predicted to increase the risk of severe hypertension when given with lisdexamfetamine. Both lisdexamfetamine and safinamide can increase the risk of serotonin syndrome.	
Selegiline	Severe	Theoretical	Selegiline is predicted to increase the risk of severe hypertension when given with lisdexamfetamine. Both lisdexamfetamine and selegiline can increase the risk of serotonin syndrome.	Manufacturer advises avoid
Tipranavir	Severe	Theoretical	Tipranavir is predicted to increase the exposure to lisdexamfetamine.	
Tranylcypromine	Severe	Anecdotal	Tranylcypromine is predicted to increase the risk of a hypertensive crisis when given with lisdexamfetamine. Both lisdexamfetamine and tranylcypromine can increase the risk of serotonin syndrome.	Manufacturer advises avoid and for 14 days after stopping the MAOI.
Chlorpromazine	Moderate	Study	Chlorpromazine is predicted to decrease the effects of lisdexamfetamine and lisdexamfetamine is predicted to decrease the effects of chlorpromazine.	
Fluphenazine	Moderate	Study	Fluphenazine is predicted to decrease the effects of lisdexamfetamine and lisdexamfetamine is predicted to decrease the effects of fluphenazine.	
Levomepromazine	Moderate	Study	Levomepromazine is predicted to decrease the effects of lisdexamfetamine and lisdexamfetamine is predicted to decrease the effects of levomepromazine.	

Pericyazine	Moderate	Study	Pericyazine is predicted to decrease the effects of lisdexamfetamine and lisdexamfetamine is predicted to decrease the effects of pericyazine.	
Prochlorperazine	Moderate	Study	Prochlorperazine is predicted to decrease the effects of lisdexamfetamine and lisdexamfetamine is predicted to decrease the effects of prochlorperazine.	
Promazine	Moderate	Study	Promazine is predicted to decrease the effects of lisdexamfetamine and lisdexamfetamine is predicted to decrease the effects of promazine.	
Trifluoperazine	Moderate	Study	Trifluoperazine is predicted to decrease the effects of lisdexamfetamine and lisdexamfetamine is predicted to decrease the effects of trifluoperazine.	

References

- NICE Evidence summary [ESNM19] - Attention deficit hyperactivity disorder in children and young people: lisdexamfetamine dimesylate
- NICE guideline [NG87] - Attention deficit hyperactivity disorder: diagnosis and management
- Summary of product characteristics for lisdexamfetamine (Elvanse® & Elvanse Adult)

Appendix 1:

Effective Shared Care Agreement (ESCA)

Lisdexamfetamine

Approved for Solihull CCG only.

For the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme.

Please refer to BSSE APC formulary website for complete document.

BACK-UP ADVICE AND SUPPORT (To be completed by Specialist team)

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Transitioning patients Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary	Adult service consultant to tick and sign please

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

To be completed by the General Practitioner:

I agree to participate in this shared care agreement for the treatment of the below named patient with lisdexamfetamine in Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme

General Practitioner
Name (please print)_____Signature _____Date_____

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant.

In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement.

GP Prescribing System	Read Code	Description		GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care