NHS
Pan Mersey
Area Prescribing Committee

SHARED CARE FRAMEWORK

The Pan Mersey Area Prescribing Committee recommends the prescribing of LISDEXAMFETAMINE (Elvanse®▼) for ADHD in accordance with NICE NG87.

SHARED CARE

NHS Halton CCG for the treatment of adults only
NHS Knowsley CCG for the treatment of adults only
NHS St Helens CCG for the treatment of adults only
NHS Warrington CCG for the treatment of adults only

Background

Attention deficit hyperactivity disorder (ADHD) is a chronic, neurodevelopmental disorder associated with inattention, hyperactivity and impulsiveness.

The National Institute for Health and Clinical Excellence (NICE) issued a clinical guideline, Attention Deficit Hyperactivity Disorder: diagnosis and management (NG87) in 2018. This document advises that treatment for ADHD should only be initiated by a healthcare professional with expertise in ADHD and should be based on a comprehensive assessment and diagnosis. Continued prescribing and monitoring of drug therapy may be performed by the primary care clinicians, under shared care arrangements.

NICE NG87 states: 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.

Symptoms of ADHD can persist into adulthood in about two thirds of all patients. For patients transitioning into adulthood, specialists should ensure appropriate arrangements are made for referral into adult services. In such circumstances a new shared care agreement will need to be made between the primary care clinician and the new specialist provider.

Treatment must be under the supervision of an appropriate specialist in childhood, adolescent and/or adult behavioural disorders.

Mode of action

Lisdexamfetamine is a pro-drug of the stimulant dexamfetamine. Its actions are thought to be due to its ability to block the reuptake of noradrenaline and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space.

Licensed Indications

Lisdexamfetamine is indicated as part of a comprehensive treatment programme for attention deficit hyperactivity disorder in children and adolescents aged 6 years and over when response to previous methylphenidate treatment is considered clinically inadequate.

Lisdexamfetamine is also indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adults.

Locally agreed off-label use

Children aged 5-6 years

Initiation and ongoing dose regime

It is the responsibility of the specialist to initiate and stabilise patients on lisdexamfetamine.

Transfer of monitoring and prescribing to Primary care is after the dose has been stabilised and the patient has been reviewed by the specialist. The duration of treatment will be determined by the specialist based on clinical response and tolerability.

Dosing information

All dose adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.

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. If paradoxical aggravation of symptoms or other intolerable adverse events occur, dosage should be reduced or discontinued.

The starting dose is 30mg taken once daily in the morning. When in the judgment of the clinician a lower initial dose is appropriate, patients may begin treatment with 20mg once daily in the morning. The dose may be increased by 10mg or 20mg increments, at approximately weekly intervals. The maximum recommended dose is 70mg/day.

Dose adjustments may be necessary in severe renal insufficiency and the maximum dose should not exceed 50mg/day.

The initial dose should be titrated against symptoms and adverse effects in line with the BNF or BNF for Children over 4–6 weeks. Doses should be gradually increased until dose optimisation is achieved, that is, reduced symptoms, positive behaviour change, improvements in education, employment and relationships, with tolerable adverse effects[2].

Ongoing prescribing

Shared Care may only be commenced following initiation, stabilisation and review of treatment. In addition, formal agreement must have been received from the primary care prescriber. Termination will be the responsibility of the specialist.

Review the use of lisdexamfetamine at least once a year and discuss with the patient (and their families and carers as appropriate) whether the medication should be continued (NICE NG87).

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 will be undertaken and supervised by the specialist who will advise the patient and GP of the outcome.

Baseline investigations and initial monitoring to be undertaken by the specialist

Baseline (Pre-Treatment Screening)

Before starting medication for ADHD, a full assessment should be completed which should include:

- a review to confirm they continue to meet the criteria for ADHD and need treatment
- a review of mental health and social circumstances, including:
    - presence of coexisting mental health and neurodevelopmental conditions

  - current educational or employment circumstances
  - risk assessment for substance misuse and drug diversion
  - care needs
- a review of physical health, including:
  - a medical history, taking into account conditions that may be contraindications for specific medicines
  - current medication
  - height and weight (measured and recorded against the normal range for age, height and sex)
  - baseline pulse and blood pressure
  - A cardiovascular assessment.

An electrocardiogram (ECG) is not needed before starting lisdexamfetamine, unless the person has any of the features mentioned in recommendation 1.7.5 of the NICE 2018 Attention deficit hyperactivity disorder diagnosis and management guidelines or a co-existing condition that is being treated with a medicine that may pose an increased cardiac risk.

Ongoing monitoring requirements to be undertaken by primary care

Monitoring	Frequency
Blood pressure and pulse	At every adjustment of dose or visit to specialist service and then every 6 months. Primary care – every 6 months.
Weight (in adults); Height and weight (in children and adolescents)	At every adjustment of dose or visit to specialist service or at least every 6 months. Primary care – every 6 months. Weight every 3 months in children 10 years and under
Compliance, indication of abuse, misuse or diversion	Every 6 months
Side effects	Every 6 months
Clinical need, benefit, side effects	Annual Review by Specialist

Cardiovascular monitoring (blood pressure and heartrate) should be undertaken before and after each dose adjustment.

Refer to 'Adverse Drug Reactions' section for advice and actions to be taken.

Pharmaceutical aspects

Route of administration

Oral

Formulation

Hard capsules containing 20mg, 30mg, 40mg, 50mg, 60mg and 70mg of lisdexamfetamine dimesylate.

Administration details

Lisdexamfetamine 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. If the contents include any compacted powder, a spoon may be used to break apart the powder in the soft food or liquid. Capsule contents should be stirred until completely dispersed and the entire mixture of soft food or liquid consumed immediately; it should not be stored.

In the event of a missed dose, dosing can resume the next day. Afternoon doses should be avoided because of the potential for insomnia.

Contraindications

For a comprehensive list consult the BNF or Summary of Product Characteristics.

Significant drug interactions

For a comprehensive list consult the BNF or Summary of Product Characteristics.

Adverse effects and Management

For a comprehensive list consult the BNF or Summary of Product Characteristics.

The most common adverse effects include:

- Metabolic effects such as weight loss and growth restriction. In children, slow weight gain and a reduction in attained height and suppression of growth during prolonged use.
- Psychiatric effects such as insomnia, agitation, aggression, anxiety, labile affect, tics, mood swings and depression.
- Central nervous system effects such as dizziness, sleep disturbances, dyskinesia, psychomotor hyperactivity, irritability and headache.
- Cardiovascular system effects such as increased blood pressure, tachycardia, palpitations and cardiomyopathy.
- Gastrointestinal effects such as dry mouth, diarrhoea, constipation, abdominal cramps, nausea, vomiting and reduced appetite.
- Urogenital effects such as sexual dysfunction.
- Respiration disorders such as dyspnoea.
- Ophthalmological effects such as blurred vision and mydriasis.
- Other disorders such as pyrexia and fatigue.

In children, parents/patients will have been advised by the ADHD specialist to report any suspected side effects directly to them. GPs should refer any patients with suspected side effects to the ADHD specialist irrespective of the advice in the following table.

Adverse effect	Management
Sustained resting tachycardia, severe chest pain, dyspnoea and unexplained syncope or other symptoms suggestive of cardiac disease.	Discontinue treatment. Seek prompt cardiac specialist advice and notify the initiating specialist team
Clinically significant increases in blood pressure, arrhythmia.	Exclude other causes and seek ADHD specialist advice. Dose reduction may be appropriate.
Reduced weight and growth retardation.	Continue treatment. Provide advice on healthy diet. The patient should be advised to consider taking additional meals or snacks early in the morning or late in the evening when the effects of the drug have worn off. Refer to a dietician if appropriate. If weight loss becomes a concern, seek ADHD specialist advice.
Increase in seizure frequency or new-onset seizures.	Refer to the initiating specialist team. Discontinuation or switching of treatment may be appropriate.
Development or worsening of psychiatric disorders including psychotic or manic symptoms, aggressive or hostile behaviour, anxiety, agitation, motor or vocal tics and suicidal ideation.	Refer to the initiating specialist team. Depending on symptoms, discontinuation of treatment, dose reduction or switching may be considered by the ADHD specialist.
Central nervous system effects such as dizziness, dyskinesia, psychomotor hyperactivity and headache.	Usually temporary. If persisting, refer to ADHD specialist. Dose reduction or discontinuation of treatment may be appropriate.

Severe blood, kidney and liver and skin disorders.	Exclude other causes. Repeat blood tests for confirmation. Seek ADHD specialist advice if the adverse effect is secondary to the drug. Discontinuation of treatment may be considered.
Glaucoma or other severe visual disturbances.	Seek ophthalmological advice and notify the ADHD specialist Team. Discontinuation of treatment may be considered by the ADHD specialist.
Diarrhoea, abdominal cramps, nausea, vomiting	Continue treatment. May be alleviated by administering medication with food. Exclude other causes. Seek ADHD specialist advice if symptoms become severe. Dose reduction or discontinuation of treatment may be considered.
Insomnia	Usually transient. Continue treatment. Provide sleep hygiene advice. Timing of doses may need to be adjusted with ADHD specialist advice.

Lisdexamfetamine is a black triangle drug. Any suspected adverse reaction to lisdexamfetamine should be reported to the MHRA via the "Yellow Card" scheme on http://yellowcard.mhra.gov.uk

Advice to patients and carers

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 drugs.

The patient should be advised to report any of the following signs or symptoms to their GP without delay:

Symptoms suggestive of cardiac or psychiatric disorders or seizures.

It is advisable for patients to abstain from alcohol during treatment as alcohol may exacerbate the CNS side effects of lisdexamfetamine

In children, parents/patients will have been advised by the ADHD specialist to report the above signs or symptoms directly to them.

WARNING: Lisdexamfetamine can also cause dizziness, drowsiness and visual disturbances. These can impair a patient's ability to drive safely. This medicine is in the list of drugs included in regulation under 5a of the Road Traffic Act 1988. It is an offence to drive while under the influence of this medicine.

Pregnancy and breastfeeding

Seek advice from initiating specialist for prescribing decision.

Specialist contact information

If stopping medication or needing advice, refer to shared care agreement (Appendix 2)

Additional information

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.

References

1. Summaries of Product Characteristics (Elvanse®▼), accessed December 2019; Lisexamfetamine -emc
2. NICE guidelines (NG87) March 2018: Attention deficit hyperactivity disorder: diagnosis and management https://www.nice.org.uk/guidance/ng87
3. NICE CKS – ADHD https://cks.nice.org.uk/attention-deficit-hyperactivity-disorder

4. British National Formulary. Accessed December 2019. BNF British National Formulary - NICE
5. British National Formulary for Children. Accessed December 2019. BNF for Children British National Formulary - NICE

To be read in conjunction with the following documents.

1. Policy for Shared Care
2. Shared care agreement.

Appendix 1

Policy for Shared Care

Shared care is only appropriate if it provides an optimum solution for the patient and it meets the criteria outlined in the Shared Care section of the Pan Mersey Definitions and Criteria for Categorisation of Medicines in the Pan Mersey Formulary document.

Before prescribing responsibilities are transferred to primary care:

- Prescribing responsibility will only be transferred when the consultant and the patient's GP agree that the patient's condition is stable.
- All information required by the shared care framework for the individual medicine has been provided to the patient's GP.
- Patients will only be referred to the GP once the GP has agreed to the Shared Care Agreement and returned signed copies.

Inherent in any shared care agreement is the understanding that participation is at the discretion of the GP, subject to the availability of sufficient information to support clinical confidence.

Specialist Responsibilities in Shared Care

- To initiate the medicine, prescribe, monitor for toxicity and efficacy as described by the shared care framework until the patient is stabilised.
- To ensure the patient or their carer:
    - Is counselled with regard to the risks and benefits of the medicine.
    - Provide any necessary written information to the patient with regard to the individual medicine including patient information leaflets on individual drugs.
    - Obtain and document informed consent from the patient when any medicines is prescribed for an off-label indication for any condition
- To be familiar with the shared care framework.
- To provide all information to the patient's GP as required by the shared care framework when prescribing responsibility is initially transferred and at any subsequent times as necessary for safe and effective treatment of the patient.
- To assess the patient regularly as necessary for the duration of therapy.
- To review the patient promptly if required by the GP concerned.
- To meet any additional requirements as required by the individual medicine shared care framework.
- To communicate failure of a patient to attend a routine hospital review and advise the GP of appropriate action to be taken.

Primary Care Responsibilities in Shared Care

- To reply to a written request for Shared Care within 21 days ensuring both copies of the Shared Care Agreement are signed if appropriate.

If agreeing to shared care, the GP is asked to:

- To provide prescribe or manage and monitor the medicine as advised by the Specialist and in line with the individual Shared Care Framework.
- To review the patient as required by the Shared Care Framework
- To make appropriate and contemporaneous records of prescribing and/or monitoring and to note the existence of the Shared Care Agreement on the patient`s clinical record. A READ code of "6652 Shared Care-Specialist/GP" can be used.
- To be familiar with the individual Shared Care Framework.
- To report any adverse effects of treatment to the specialist team.
- To inform the Specialist of any relevant change in the patient's circumstances.
- To seek Specialist advice as appropriate.
- To meet any additional requirements as required by the individual Shared Care Framework.
- To respond to Specialist communication relating to any change or addition to the patient's treatment covered by the Shared Care Agreement.

Where the GP wishes to withdraw prescribing, for example when the patient fails to attend for monitoring, they need to give the specialist team a minimum of 14 days' notice of their need to resume responsibility for prescribing. The specialist is required to acknowledge this request within the 14-day time period.

Appendix 2

Shared Care Agreement

Lisdexamfetamine

Request by Specialist Clinician for the patient's GP to enter into a shared care agreement

Part 1

To be signed by Consultant / Prescribing member of Specialist Team

Date _____

Name of patient_____

Address _____

_____

Patient NHS No _____

Patient hospital unit No _____

Diagnosed condition _____

Dear Dr_____

I request that you prescribe

Lisdexamfetamine

for the above patient in accordance with the enclosed shared care framework.

Last Prescription Issued: ..... / ..... / ..... Next Supply Due: ..... / ..... / .....

I confirm that the patient has been stabilised and reviewed on the above regime in accordance with the Shared Care Framework and Policy.

I confirm that if this is a Shared Care Agreement for a drug indication which is unlicensed or off label, informed consent has been received.

Details of Specialist Clinicians

Name _____Date_____

Consultant / Prescribing member of Specialist Team *circle or underline as appropriate

Signature _____

In all cases, please also provide the name and contact details of the Consultant.

When the request for shared care is made by a prescriber who is not the consultant, it is the supervising consultant who takes medico-legal responsibility for the agreement.

Consultant: _____

Contact details:

Shared Care Framework

Telephone number: _____Ext:_____

Address for return _____

of documentation

_____

_____

Please add patient addressograph here

Part 2

To be completed by Primary Care Clinician

I agree to prescribe _____for the above patient in accordance with the enclosed shared care framework.

GP signature _____Date _____

GP name _____Please print

GP: Please sign and return a copy within 21 calendar days to the address above

OR

GP- If you do not agree to prescribe, please delete the section above and provide any supporting information as appropriate below: