SHARED CARE GUIDELINE

Pennine Care NHS
NHS Foundation Trust

Title: Shared Care Guideline for the prescribing and monitoring of lisdexamfetamine (Elvanse) for the treatment Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents**.**	
Scope: Pennine Care NHS Foundation Trust To support an individualised care pathway where this has been previously agreed with the GP only	**Version:** Version 1
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Author(s)/Originator(s)	Pennine Care NHS Foundation Trust
To be read in conjunction with the following documents:	BNF -current edition BNF for children -current edition Summary of Product Characteristics (SPC) Pharmaceutical company's patient information leaflet (PIL)
Authorised by:	Drugs and Therapeutics Committee
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1 Scope

Pennine Care NHS Foundation Trust
To support an individualised care pathway where this has been previously agreed with the GP only.

2 Introduction

ADHD is a neuropsychological / developmental condition with secondary behavioural, social and educational difficulties. ADHD is defined by the 'core' symptoms of inattention, hyperactivity and impulsiveness. To make a diagnosis, the core symptoms should be pervasive, present before age 7 years, and not better accounted for by other psychiatric or developmental disorders.
Diagnosis of ADHD should be based on comprehensive assessment conducted by child / adolescent psychiatrist (or nominated specialist nurse/

advanced practitioner in supervision with psychiatrist), or by a Paediatrician with expertise in ADHD.

NICE recommends that the choice of medication for the treatment for ADHD should be based on: presence of co-morbid conditions, different adverse effects of the drugs, compliance, potential for drug diversion with stimulants, and preference of child and carer (NICE Clinical Guideline 72 September 2008).

3 Treatment of Clinical Condition using Lisexamfetamine

Licensed Indication

Lisdexamfetamine dimesylate (Elvanse®) is licensed in the UK for use as part of a comprehensive treatment programme for the treatment of ADHD in children aged 6-18 years when response to previous methylphenidate hydrochloride treatment is considered clinically inadequate.

Within Pennine Care NHS Foundation Trust, lisdexamfetamine may be prescribed **second or third line** in the treatment of ADHD :

a. when methylphenidate including modified release preparations have not been successful or well tolerated **and**
b. where drug diversion is not a significant risk.

Lisdexamfetamine may be considered as a second line option for patients who have established swallowing difficulties.

Treatment with lisdexamfetamine will be initiated and supervised by a Consultant. Continued prescribing and monitoring can be performed by GPs under this shared care agreement.

Pre-treatment screening:
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 height and weight on a growth chart.

Monitoring required:

- Pulse and blood pressure should be measured and recorded on a chart at every dose adjustment and then at least every 6 months.
- Height, weight and appetite should be recorded at least every 6 months on a growth chart.
- 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 requiring long term therapy should be carefully monitored for the risk of diversion, misuse and medication abuse.

4 Product Information

Lisdexamfetamine is currently classified as a prescription-only medicine (POM) in the UK. However, the drug's legal status is scheduled for review by the Home Office and prescribers should be aware that it may be reclassified as a Schedule 2 Controlled Drug (CD) in the future. In the interim, the Royal Pharmaceutical Society is advising pharmacists to treat it as if it were a Schedule 2 CD.

Note: Methylphenidate and dexamfetamine are classified as POM CNS stimulants and Schedule 2 Controlled Drugs by the Home Office and listed as such in the British National Formulary (BNF).

The capsules can be taken whole, with or without food. For patients who have swallowing difficulties, the capsules may be opened and the entire contents dissolved in a glass of water. This does not affect the long acting nature of the medication.

Administration is usually continuous. However where ADHD symptoms are well tolerated and managed at home, families may elect to use medication during term times/ on school days only.

LISDEXAMFETAMINE DIMESYLATE

Name	**Dosage** **6 – 18 years**
Lisdexamfetamine (Elvanse®) 30mg. 50mg, 70mg capsules	Initially 30mg once daily in the morning. Can be increased by 20mg at weekly intervals. Maximum dose 70mg daily

5 Regimen Management

Aspects of care for which the Consultant/ Specialist Team is responsible.
Child and Adolescent Psychiatrist, Paediatrician.

- Direct assessment or supervision of specialist team assessment, diagnosis of ADHD, evaluation of prior treatment, and rationalisation of treatment with medication.

- Completion of ADHD Pre-medication Assessment Pro-forma (Appendix 1) Pre-treatment screening: baseline blood pressure and pulse, height and weight, measured and plotted on appropriate charts.

- Documentation of concomitant medicines; past and present medical and psychiatric disorders/symptoms; family history of sudden cardiac death, unexplained death, or malignant arrhythmia

- A cardiovascular examination is required if a patient presents with cardiovascular symptoms or has a significant family history of cardiac illness. An ECG is also recommended for those with a significant family history of cardiac illness or abnormal findings on cardiovascular examination. In this circumstance, specialist advice or assessment should be sought prior to commencing medication (see ADHD Pre-medication Assessment Pro-forma).

- Informing patient/ carer of diagnosis, care plan, treatment including side effects use of Patient Information Leaflets (PILs), user-friendly information for children/ adolescents.
- Treatment decisions being shared between the patient, parents and the Consultant.
- Informing the patient/ parents of the latest regulatory advice.
- Ascertaining patient/ family's commitment to safe storage and handling of medication.
- Asking the General Practitioner (GP) if they would be willing to participate in shared care.
- Initiation and titration of medication to a suitable dose or provide instructions/directions to the GP for titration of medication to a suitable dose <u>where agreed</u>
- Written correspondence to GP from summarising progress and recommendations for continued treatment.
- Ensure clear arrangements for GP back up, advice and support.
- Promoting access to any appropriate supporting therapies, carer education, and appropriate school liaison.

- Minimum 6 monthly Specialist Team review appointments and as clinically indicated. Follow up all aspects of progress, plus height, weight, appetite, blood pressure and pulse. Monitor for signs of diversion, misuse and abuse of medication.

- Development of new or worsening of pre-existing, psychiatric symptoms should be monitored at every dose adjustment and then at least every 6 months, and at every visit.

- Reporting suspected adverse events to the GP and the MHRA via the Yellow Card scheme to www.mhra.gov.uk/yellowcard

- Consideration (and evaluation) of annual 'drug holiday' to determine continued benefit.

- Discontinuation of treatment or transfer if appropriate.

- If a patient is to be discharged from specialist follow-up due to recurrent failure to attend appointments, the specialist team should write to the GP informing them of this plan and clarifying whether continued GP prescribing is recommended. Patients should not normally be continued on this medication without specialist monitoring.

Conditions of assuming responsibility by the GP

- Communication of satisfactory baseline physical checks.

- Satisfactory directions/instructions for titration to optimum dosage, and response to treatment.

	Consultant	**Usual GP**
Then 6 monthly follow up of height, weight, BP and pulse	Yes	N/A
If changes noted	Amend dose accordingly	Refer to Consultant

Aspects of care for which the GP is responsible

- Replying to requests for shared care as soon as possible.
- Continued prescribing of medication in the community under guidance of Consultant/ Specialist Team.
- To undertake tests appropriate to primary care, during treatment, if requested to do so by the Consultant.
- Refer to the Consultant/Specialist Team for queries regarding treatment/side effects, and concerns about compliance or suspected drug misuse.
- Ensure compatibility of lisdexamfetamine with concomitant prescribed medication.
- Stopping treatment on the advice of the Consultant/Specialist team.

- Continuation without specialist review is not recommended.
- Reporting noted adverse events to the Consultant/Specialist Team and the MHRA via the Yellow Card scheme to www.mhra.gov.uk/yellowcard

6 Summary of cautions, contra-indications, side effects and interactions

Please refer to the current edition of the BNF and BNF for Children and Summary of Product Characteristics (SPCs) of the individual drugs for the latest and full list of contraindication, cautions, side effects and interactions.

Contraindications

- symptomatic cardiovascular disease including moderate to severe hypertension and advanced arteriosclerosis structural cardiac abnormalities
- hyper excitability or agitated states
- hyperthyroidism, thyrotoxicosis
- glaucoma

Cautions

- anorexia;
- history of cardiovascular disease or abnormalities
- psychosis or bipolar disorder
- monitor for aggressive behaviour or hostility during initial treatment
- history of drug or alcohol abuse
- may lower seizure threshold (discontinue if seizures occur)
- tics and Tourettes syndrome (use with caution) - discontinue if tics occur
- susceptibility to angle-closure glaucoma
- avoid abrupt withdrawal
- data on safety and efficacy of long-term use not complete
- acute porphyria

Side effects

- nausea
- decreased appetite
- vomiting, diarrhoea
- dry mouth,
- abdominal cramps,
- dyspnoea, sleep disturbances,
- tics,
- aggression,
- headache, dizziness, drowsiness,
- mydriasis,
- labile mood,

- weight loss,
- pyrexia, malaise,
- growth restriction in children
- anorexia,
- tachycardia, palpitation, hypertension,
- logorrhoea, anxiety, paranoia, restlessness,
- depression, dysphoria,
- dermatillomania, mania, hallucination,
- sweating,
- tremor,
- visual disturbances,
- sexual dysfunction,
- rash;
- angle-closure glaucoma;
- cardiomyopathy,
- euphoria,
- seizures
- central stimulants have provoked choreoathetoid movements and dyskinesia, and Tourette syndrome in predisposed individuals

d) Interactions

- MAOI's and tricyclic antidepressants
- Barbiturates
- Opioids - increased analgesic effects of morphine and other opioids but reduced sedative and respiratory depressant effects.
- Ascorbic acid and other agents and conditions (diets high in fruits and vegetables, urinary tract infections and vomiting) that acidify urine increase urinary excretion may decrease the half-life of amfetamines.

7 Special considerations

Special consideration will be made when issues of tolerance, inconsistent response to treatment, patient non-concordance or pre-existing medical conditions occur.

The misuse potential of lisdexamfetamine will be minimised by careful selection of patients for treatment, a maximum of 28 days treatment being prescribed at any one time, prompt discussion between GP and specialist service with review or termination of treatment in event of non-attendance or suspected drug misuse.

8 Back-up care available to GP from Hospital, including emergency contact procedures and help line numbers.

Written correspondence following Consultant/ Specialist Team appointments, specifically detailing the next review date and any dose adjustments.

Telephone advice/ information from the Consultant / Specialist Team during office hours, and plans for earlier review by team if necessary.

Dr [insert text here]_____

Contact number: [insert text here] _____

Hospital: [insert text here]_____

Out of hours on call/ emergency mental health service contactable through hospital switchboards.

9 Statement of agreement

This document outlines the suggested care pathway of the named patient. If you are unable to agree to the sharing of care and prescribing the suggested medication, please make this known to the Consultant within 14 days stating the nature of your concern.

10 Written information provided to the patient

- Pennine Care NHS Foundation Trust Patient Information Leaflet
- NICE Technology Appraisal 98: Information for the public

11 Supporting References

- NICE Clinical Guideline 72. Attention deficit hyperactivity disorder. September 2008 www.nice.org.uk/CG072
- NICE Evidence Summary for New Medicines for lisdexamfetamine (ESNM19) – May 2013
- NICE Technology Appraisal 98: Methylphenidate, atomoxetine and dexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and adolescents March 2006. www.nice.org.uk/TA098
- BNF Number 65, March-September 2013.
- BNF for Children, 2012-2013.
- Summary of Product Characteristics. www.medicines.org.uk. Accessed June 2013
- MHRA. Drug Safety Update. Volume 2. Issue 8. www.mhra.gov.uk. Accessed June 2013.

ADHD PRE-MEDICATION ASSESSMENT PRO FORMA Appendix 1

Name of Child: _____ **Date:**_____

DOB: _____ **RT NO:** _____

Consultant/Psychiatrist: _____**Case Worker:**_____

Please clarify if previous or current history

	Child	**Family**
Significant anxiety		
Expresses suicidal ideas		
Low mood or depression		
Angina/MI under 55 or history of sudden death		
High or low BP/Pulse		
Arrhythmia		
History of exercise syncopy or cardiovascular Symptoms		
Epilepsy		
Drug/alcohol misuse or dependency		
Tics/Tourettes		
Thyroid Disorder		
Glaucoma		
Kidney Disease		
Liver Disease		

Drug allergies:

Other medication prescribed:

Clinical examination:

Height:_____ **Centile** _____

Weight:_____ **Centile** _____

Plot on centile charts

B/P: _____**Pulse** _____

<u>Cardiovascular examination</u>

If family history of sudden death, MI under 55 or young person with history of cardiovascular symptoms e.g. exercise syncope or breathlessness.

Options:

1. CAMHS, including documentation of findings.
2. PAEDS. Referral
3. GP. Referral

ECG if abnormal physical examination or significant family history of cardiovascular illness. Seek paediatric advice or assessment prior to commencing treatment.