SHARED CARE GUIDELINE FOR PRESCRIBING LISDEXAMFETAMINE FOR THE TREATMENT OF ADHD

INDICATION

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).

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 the pan-Dorset formulary, lisdexamfetamine has been classified as an amber drug which may be prescribed **second or third line** in the treatment of ADHD where swallowing tablets is an issue or for the younger aged child. Treatment with lisdexamfetamine will be initiated and supervised by a Child and adolescent consultant or paediatrician. Continued prescribing and monitoring can be performed by GPs under this shared care agreement:

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.

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.

Product Information

Lisdexamfetamine as well as 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 or on school days only.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of lisdexamfetamine can be shared between the specialist setting and the patient's GP (if different). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is 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. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

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

REFERRAL AND INITIATION

Specialist Responsibilities which may be primary, intermediate or secondary care based	
1	Direct assessment or supervision of specialist team assessment, diagnosis of ADHD, evaluation of prior treatment, and rationalisation of treatment with medication.
2	Documentation of concomitant medicines; past and present medical and psychiatric disorders/symptoms; family history of sudden cardiac death, unexplained death, or malignant arrhythmia
3	Informing patient/ carer of diagnosis, care plan, treatment including side effects use of Patient Information Leaflets (PILs), user-friendly information for children/ adolescents
4	Treatment decisions being shared between the patient, parents and the Consultant.
5	Informing the patient/ parents of the latest regulatory advice.
6	Ascertaining patient/ family's commitment to safe storage and handling of medication including risk assessment for the potential for diversion.
7	Asking the General Practitioner (GP) if they are willing to participate in shared care.
8	Initiation and titration of medication to a suitable dose or provide instructions/directions to the GP for titration of medication to a suitable dose where agreed
9	Written correspondence to GP from summarising progress and recommendations for continued treatment.
10	Ensure clear arrangements for GP back up, advice and support.
11	Promoting access to any appropriate supporting therapies, carer education, and appropriate school liaison.
12	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. Report any concerns re. excessive or inappropriate prescribing to the Trust Accountable Officer.
13	Reporting any suspected adverse events to the GP and the MHRA via the Yellow Card scheme to www.mhra.gov.uk/yellowcard, ▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.
14	Consideration (and evaluation) of annual 'drug holiday' to determine continued benefit.
15	Discontinuation of treatment or transfer if appropriate.
16	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

Specialist Responsibilities which may be primary, intermediate or secondary care based	
	normally be continued on this medication without specialist monitoring.

General Practitioner Responsibilities (where initiation is within a specialist setting and prescribing has been transferred	
1	To undertake tests appropriate to primary care, during treatment, if requested to do so by the Consultant with communication of satisfactory baseline physical checks
2	Satisfactory directions/instructions for titration to optimum dosage, and response to treatment. Then Refer to Consultant any changes in follow up of height, weight, BP and pulse
3	Replying to requests for shared care as soon as possible.
4	Continued prescribing of medication in the community under guidance of Consultant/ Specialist Team.
5	Refer to the Consultant/Specialist for queries regarding treatment/side effects, and concerns about compliance or suspected drug misuse
6	Ensure compatibility of lisdexamfetamine with concomitant prescribed medication.
7	Stopping treatment on the advice of the Consultant/Specialist team.
8	Continuation without specialist review is not recommended. Report any concerns re. excessive or inappropriate prescribing to Manda Coppage, at NHS England, Wessex Local Area Team.
9	Reporting noted adverse events to the Consultant/Specialist Team and the MHRA via the Yellow Card scheme to www.mhra.gov.uk/yellowcard. ▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Patient's role (or that of carer)	
1	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2	Attend appropriate consultant and GP appointments.
3	Share any concerns in relation to treatment.
4	Use written and other information on the medication.
5	Seek help urgently if suffering suspected side effects, or otherwise unwell.

SUPPORTING INFORMATION

Monitoring

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.

Dosage and Administration

	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

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

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.

This list is not exhaustive. The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

Drug costs (BNF 66):
30mg caps £58.24 (28)
50mg caps £68.60 (28)
70mg caps £83.16 (28)

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References

1. Summary of Product Characteristics for Elvanse capsules accessed via http://www.medicines.org.uk/emc/medicine/27442/SPC/Elvanse+30mg%2c+50mg+%26+70mg+Capsules%2c+hard/ accessed 17/1/2014
2. NICE clinical guideline 72, sep 2008 http://guidance.nice.org.uk/CG72/Guidance