

**Cardiff & Vale (C&V) UHB Corporate Medicines Management Group (c MMG)**

**SHARED CARE**

**DRUG: LISDEXAMFETAMINE**

**PROTOCOL NUMBER: CV 57**

**INDICATION:** Attention deficit hyperactivity disorder (ADHD) as part of a comprehensive treatment programme in children aged 6 years of age and over

In young people whose symptoms persist into adulthood and who have shown clear benefit from treatment, it may be appropriate to continue treatment into adulthood.

**General guidance**

This protocol sets out details for the shared care of patients taking lisdexamfetamine and should be read in conjunction with the General Guidelines for Shared Care. Sharing of care requires communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **The doctor who prescribed the medication legally assumes responsibility for the drug and the consequences of its use.** The prescriber has a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should also keep up to date with the relevant guidance on the use of the medicines and on the management of the patient's condition.

Lisdexamfetamine (Elvanse) is 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 ADHD treatment is considered clinically inadequate. [Drug Treatment for ADHD - Flowchart](#)

Lisdexamfetamine dimesylate is a pharmacologically inactive pro-drug that is converted into the central nervous system stimulant, dexamfetamine.

Lisdexamfetamine can be dissolved in water and could be considered in a child unable to swallow capsule contents in food.

Treatment must be under the supervision of a specialist in childhood and/or adolescent behavioural disorders or adult psychiatrist for continuation into adulthood. Diagnosis should be made according to DSM-IV criteria or the guidelines in ICD-10 and should be based on a complete history and evaluation of the patient. Diagnosis cannot be made solely on the presence of one or more symptom.

Adequate diagnosis requires the use of medical and specialised psychological, educational, and social resources. A comprehensive treatment programme typically includes psychological, educational and social measures as well as pharmacotherapy and is aimed at stabilising children with a behavioural syndrome characterised by symptoms which may include chronic history of short attention span, distractibility, emotional lability, impulsivity, moderate to severe hyperactivity, minor neurological signs and abnormal EEG. Learning may or may not be impaired.

The decision to use this medication must be decided upon a very thorough assessment of the severity of ADHD symptoms in relation to the child's age, potential for abuse, diversion or misuse.

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.

## **Responsibilities**

### **A. Consultant responsibilities**

1. When treatment is **initiated** send Shared Care request form with Shared Care Protocol to GP.
2. Initiate therapy following full discussion with the patient/carer of different treatment options, benefits and risks.
3. Comprehensive baseline assessment, initial prescribing and baseline and continued monitoring
4. Titrate lisdexamfetamine adjusting dose as appropriate and undertake monitoring of clinical response and side effects.
5. Liaise with GP, school and any other agency involved with the patient, and provide a comprehensive treatment programme for the patient
6. When a GP positive response to SC has been received and patient has been stabilised send a letter to GP "handing over" the Shared Care of the patient to the GP.
7. Respond to any request from GP to review the patient due to adverse effects of therapy.
8. Advise the GP on continuing or stopping lisdexamfetamine following medical review of the patient and associated drug therapy
9. Notify GP if patient is failing to attend for appropriate monitoring and advise GP on appropriate action.
10. Review patient at 18 years of age and refer to appropriate adult services if patient is to continue on lisdexamfetamine. Advise GP of decision.

### **B. GP responsibilities.**

1. Within one week of receipt return the completed Shared Care request form to indicate whether or not willing to undertake shared care.
2. Prescribe lisdexamfetamine as part of the shared care agreement.
3. Monitor the general health of the patient
4. Report adverse effects of therapy to the consultant and the Medicines and Health products Regulatory Agency (MHRA)
5. Act on advice provided by the Consultant if patient does not attend for appropriate monitoring.

\*monitoring will be undertaken by the Secondary Care Health Professional until the patient is stable on treatment and at least every 6 months thereafter. If the GP

becomes aware in the interim that the patient is experiencing an adverse effect or unexplained symptom such as weight loss and does not have an imminent appointment with the Consultant, they should request that the appointment be expedited.

## **Dosage Regime**

Lisdexamfetamine is available in 30mg, 50mg and 70mg hard capsules

The starting dose (6 to 18 years) is 30mg once daily in the morning. The dose may be increased by 20mg increments, at approximately weekly intervals up to a maximum dose of 70mg once daily. The lowest effective dose should be used for maintenance treatment.

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 or orange juice or mixed with a soft food such as yoghurt. This does not affect the long acting nature of the medication.

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

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

Where ADHD symptoms are well tolerated and managed at home, families may elect to use medication during term times or on school days only

## **Monitoring in secondary care**

\*monitoring will be undertaken by the Secondary Care Health Professional until the patient is stable on treatment and at least every 6 months thereafter. If the GP becomes aware in the interim that the patient is experiencing an adverse effect or unexplained symptom such as weight loss and does not have an imminent appointment with the Consultant, they should request that the appointment be expedited.

### Before treatment

Patients with ADHD should have a full pre-treatment assessment, which should include:

- full mental health and social assessment
- full history and physical examination, including:
  - assessment of history of exercise syncope, undue breathlessness and other cardiovascular symptoms heart rate and blood pressure (plotted on a centile chart)
  - height and weight

(plotted on a growth chart for children and young people).  
(adults would not need monitoring for weight, unless clinical concern over weight loss)  
family history of cardiac disease and examination of the cardiovascular system

- an electrocardiogram (ECG) if there is past medical or family history of serious cardiac disease, a history of sudden death in young family members or abnormal findings on cardiac examination
- risk assessment for substance misuse and drug diversion (where the drug is passed on to others for non-prescription use).
- Enquiry about history of seizures or tics

FBC or other blood tests only if clinically indicated (Stop treatment if WCC  $<4.0 \times 10^9/L$ )

Blood pressure, and heart rate should be monitored before and after each dose change and every 6 months. Sustained resting tachycardia, arrhythmia or systolic BP greater than 95<sup>th</sup> centile (or a clinically significant increase) measured on 2 occasions should prompt dose reduction and referral for assessment.

Height should be monitored 3 monthly during titration phase and thereafter at 6 monthly intervals in children and young people.

Weight should be measured at 3 and 6 months after the start of treatment, then 6 monthly thereafter in children and young people.

In children, these values should be plotted on a growth centile chart such as the Child Growth Foundation Chart (CGFC). This should be reviewed by the Specialist responsible for treatment.

In a child, if the height/weight centile falls by space equivalent to the gap between two centile lines on the CGFC, ensure patient is seen by a Consultant Paediatrician or CAMHS.

Development or worsening of psychiatric disorders should be monitored at every dose change and then at least every 6 months and every dose change.

### **Adverse effects**

Adverse reactions observed with lisdexamfetamine treatment mainly reflect side effects commonly associated with stimulant use. Very common adverse reactions include decreased appetite, nausea, insomnia, dry mouth, headache, weight decreased and upper abdominal pain.

**Interactions**

Lisdexamfetamine interacts with guanethidine, venlafaxine, MAOIs, ascorbic acid, antihypertensives, narcotic analgesics, chlorpromazine, haloperidol, lithium carbonate.

**Pregnancy**

Manufacturer advises use only if potential benefit outweighs risk

**Breast-feeding**

Manufacturer advises avoid—present in human milk

**Contraindications**

- Hypersensitivity to lisdexamfetamine or excipients
- Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days after MAOI treatment (hypertensive crisis may result)
- Symptomatic cardiovascular disease including moderate to severe hypertension and advanced arteriosclerosis structural cardiac abnormalities
- Hyperexcitability or agitated states
- Hyperthyroidism, thyrotoxicosis
- Glaucoma

**Special warnings and precautions**

As with other stimulants be aware of

- misuse, dependence or diversion and risk of drug tolerance
- cardiovascular events, cardiomyopathy
- psychosis
- exacerbation of polar disorder
- increased aggression and tics
- increased risk of seizures
- potential visual disturbance

**Date of approval      September 2015**

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