Powys Shared Care Agreement: December 2014

DEXAMFETAMINE & LISDEXAMFETAMINE DIMESYLATE

for the treatment of Attention Deficit/Hyperactivity Disorder (ADHD) in children, adolescents and adults

	✶PLEASE CHECK (POWYS FORMULARY WEBSITE ADDRESS) FOR THE LATEST VERSION OF THIS PROTOCOL✶
General guidance	This agreement outlines shared care arrangements for patients taking dexamfetamine or lisdexamfetamine dimesylate (lisdexamfetamine) for the treatment of Attention Deficit / Hyperactivity Disorder (ADHD). This Protocol does NOT cover the use of: 1. lisdexamfetamine at doses above the maximum recommended in ADHD. 2. Dexamfetamine at doses above the maximum recommended in ADHD. This Protocol should be read in conjunction with: ➢ The *Shared Care Agreement Form* (*see below*). ➢ NICE CG72 (September 2008, last modified March 2013 http://www.nice.org.uk/Guidance/CG72). *Attention deficit hyperactivity disorder: Diagnosis and management of ADHD in children, young people and adults.* **Note**: NICE CG72 incorporates recommendations from NICE TA98 and TA102. ➢ The Summary of Product Characteristics (Data Sheet) for Elvanse® see: http://www.medicines.org.uk/
1. Licensed indication	Dexamfetamine and lisdexamfetamine are indicated as a part of a comprehensive treatment programme for ADHD in children aged 6 years of age and over and adolescents, when response to previous methylphenidate treatment is considered clinically inadequate. Treatment must be under the supervision of a specialist in childhood ADHD. Diagnosis should be made according to DSM-IV criteria or the guidelines in ICD-10 or their updates, 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. 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. 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. Lisdexamfetamine treatment is not indicated in all children with this syndrome and the decision to use the drug must be based on a very thorough assessment of the severity and the chronicity of the child's symptoms in relation to the child's age. Appropriate educational intervention is essential, and psychosocial intervention is generally necessary. The decision to prescribe a stimulant is usually based on rigorous assessment of the severity of the child's symptoms, and may not wait for remedial measures. The use of lisdexamfetamine should always be used in the way according to the licensed indication and according to the prescribing/diagnostics guidelines. Treatment should be interrupted at least once a year to determine whether continuation is needed (Drug Safety Update, March 2009).
2. Background information	It has been shown that the symptoms of ADHD can, in a large proportion of cases (up to 70%) be improved by the use of stimulant medication. The medication works by stimulating inhibitory mechanisms in the brain, thereby, controlling impulsiveness and enabling the child/adolescent/adult to attend and concentrate. This enables parents, relatives, teachers, and the child/adolescent/adult to regain control of the behaviour through psychosocial, behavioural and educational strategies that run in parallel. Stimulant medication has been in use since the

	1950s and experience indicates that the benefits usually outweigh the problems that may arise. **It is essential that proper monitoring occurs.** Lisdexamfetamine is an inactice pro-drug of dexamfetamine. The pro-drug is metabolised to active dexamfetamine following absorption from the gut. Metabolism is slow, giving a prolonged effective treatment for ADHD symptoms (up to 12 hours or longer in some individuals)
3. Contraindication & Cautions	Dexamfetamine and lisdexamfetamine are contraindicated in: • Known sensitivity to lisdexamfetamine, amfetamine (i.e. sympathomimetic amines) or to any of the excipients. • Concomitant use with monoamine oxidase inhibitors (MAOI) or withing 14 days of stopping MAOI treatment • Hyperthyroidism or thyrotoxicosis • Agitated states • Symptomatic cardiovascular disease • Advanced arteriosclerosis • Moderate to severe hypertension • glaucoma **<u>Cautions:</u>** **Children < 6 years and adults** – UNLICENSED use **Abuse** – dexamfetamine and lisdexamfetamine should be used with caution in patients with known drug or alcohol dependency because of a potential for abuse, misuse or diversion (*Note* careful supervision is required during withdrawal from abusive use since severe depression may occur). Family history of **tics** or **Tourette's Syndrome** – needs careful evaluation before prescribing but is not necessarily an absolute contra-indication. **Epilepsy** (particularly poorly controlled epilepsy) - Children with well-controlled epilepsy can be considered for careful introduction of lisdexamfetamine however, in all such cases atomoxetine should be considered. Susceptibility to **angle closure glaucoma** **Renal impairment** use with caution **Agitation** or **anxiety** **Pregnancy** – females of child-bearing potential (i.e. post-menarche) should not use dexamfetamine or lisdexamfetamine unless clearly necessary. Avoid in breastfeeding. **Avoid abrupt withdrawal**
4. Dosage regimen	**Dexamfetamine and lisdexamfetamine are Schedule 2 controlled drugs and should be prescribed under the legal requirements stated in the BNF Controlled Drugs and Dependence.** All dose adjustments will be done by secondary care unless directions have been specified in the medical letter to the GP. **Dexamfetamine** **Child aged 6 to 18 years**: Initially 2.5mg two to three times a day. Increase by 5mg at weekly intervals if necessary. Usual maximum dose is 1mg/kg daily, up to 20mg (40mg daily has been required in some children). The maintenance dose can be given in 2 to 4 divided doses. If necessary dexamfetamine tablets can be halved. **Adults (initiation is unlicensed):** initially 5mg twice daily increased at weekly intervals according to response. Maximum dose 60mg daily. The maintenance dose can be given in 2 to 4 divided doses. **Lisdexamfetamine** **Child aged 6 to 18 years:** The starting dose is 30mg in the morning. The dose may be increased by 20mg at approximately weekly intervals. The maximum licensed dose is 70mg daily. Higher doses have not been studied.

	Capsules should be swallowed whole with water. Alternatively the contents of the capsule may be dissolved in a glass of water. 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. Response to the drug and dose requirement is not predictable from response to previous medications so dose must be titrated in some cases. Lisdexamfetamine is available as 30mg, 50mg and 70mg capsules and can be titrated according to response at weekly intervals.
5. Drug Interactions **Check *BNF* Appendix 1 before co-prescribing any other drug.**	MAOI's including moclobemide may cause hypertensive crisis Antihypertensives Narcotic analgesics Antipsychotics Lithium carbonate
6. Adverse drug reactions All serious adverse events should be reported to MHRA/CHM using the Yellow Card .	**Very Common** (≥ 1/10) – decreased appetite, insomnia, headache, upper abdominal pain, weight decrease. **Common** (≥ 1/100 to < 1/10) – anorexia, tic, affect lability, psychomotor hyperactivity, aggression, dizziness, somnolence, mydriasis, dry mouth, diarrhoea, nausea, vomiting, rash, irritability, fatigue, pyrexia, tremor, tachycardia, palpitations, dyspnoea, increase in blood pressure. **Less common** – refer to Summary of Product Characteristics or BNF **Careful supervision is required during withdrawal,** since this may unmask depression as well as chronic over-activity. Some patients may require long-term follow-up.
7. Baseline investigations	**To be undertaken by a specialist** A complete history should be taken, documenting: concomitant medicines; past and present medical and psychiatric disorders or symptoms; family history of sudden cardiac death, unexplained death, or malignant arrhythmia; and accurate pre-treatment height and weight on a growth chart. **i)** Physical examination for the presence of heart disease (including BP and pulse). The use of lisdexamfetamine is contraindicated in certain pre-existing cardiovascular disorders (*see section 3 above*) unless specialist paediatric cardiac advice has been obtained. **ii)** Assessment for co-existence of psychiatric and depressive disorders, as well as anxiety, agitation or tension, should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. **iii)** Assessment for co-existence of tics or Tourette's syndrome, including a family history.
8. Ongoing monitoring (see NICE CG72)	**To be undertaken in Secondary care** **i)** Height, weight and appetite (with maintenance of a growth chart). 3 and 6 months after treatment initiation then every 6 months **ii)** Blood Pressure and pulse (recorded on a centile chart). Before and after every dose change and every 6 months. **iii)** Emergence or worsening of psychiatric and depressive disorders as well as anxiety, agitation, tension or aggressive behaviour. Every 6 months. **iv)** Onset or exacerbation of motor and verbal tics. Every 6 months.
9. Specialist contact details	**Advice can be obtained from the local Child Psychiatry and Community Paediatric Services 9 to 5pm Monday to Friday** **Child psychiatry: 01874 712491 / 01686 617450** — **Community Paediatrics: via responsible Consultant Secretary**
10. Criteria for shared	Prescribing responsibility will only be transferred when:

care	➢ Treatment is for a specified indication. ➢ Treatment has been initiated and established by the Specialist Centre. ➢ The patient's initial reaction to and progress on the drug is satisfactory. ➢ The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements.
11. Responsibilities of Specialists (Secondary Care)	➢ **Complete full assessment**: diagnose and assess eligibility for drug therapy (NICECG72) as part of a treatment programme that includes psychological, behavioural and educational advice and interventions. ➢ **Confirm patient/carer understanding and consent** to treatment. ➢ **Undertake the baseline clinical valuations** (as detailed in *Section 7 above*). ➢ **Provide patient/carer with relevant information** on use, and the need for monitoring of medication. Obtain consent for any unlicensed use. Advise on side effects and the action to be taken should they occur (particularly development or worsening of anxiety, psychiatric and bipolar symptoms and tics as well as palpitations, exertional chest pain, unexplained syncope, dyspnoea, or other symptoms suggestive of heart disease). ➢ **Provide initial treatment** for 3 months or until the patient has been reassessed. ➢ **Communicate with the GP and request shared care**, advising if the prescribing request is outside of license, and specifying the **BRAND** of the medication prescribed. ➢ **Advise discontinuation** of medication if no improvement is seen after a reasonable trial. ➢ **Ensure BP, height and weight is monitored** every 6 months. ➢ **After each appointment** inform the GP of dosage schedule, monitoring measurements and progress of treatment. ➢ **Clinically review** the treatment at least annually, sending a written summary and updated treatment plan to the GP. ➢ **Inform the GP if the patient fails to attend** clearly indicating that the patient is taking lisdexamfetamine. ➢ **Provide any other advice** or information for the GP if required including rapid referral arrangements and contacts. ➢ **Consider a trial of withdrawal of medication when the condition is stable. This should be performed at least once yearly, under careful supervision.** ➢ **Ensure that monitoring responsibility is transferred** from child to adult services once the patient reaches 18 years of age. ➢ **Ensure that the service accepting the care of the patient on reaching adulthood seeks** further agreement with GP on the continued (UNLICENSED but covered by the *BNF* and *BNFc*) prescribing of lisdexamfetamine beyond childhood.
12. Responsibilities of patients/carers	➢ **Attend hospital and GP clinic appointments. Failure to attend will result in the medication being stopped (on specialist advice).** ➢ Store the medication appropriately and take responsibly. ➢ Report any adverse events immediately to their specialist or GP (particularly development or worsening of anxiety, psychiatric and bipolar symptoms and tics as well as palpitations, exertional chest pain, unexplained syncope, dyspnoea, or other symptoms suggestive of heart disease).
13. Responsibilities of Primary Care	➢ **Initial assessment and referral** (if >18 years) to Adult Psychiatry if not under CAMHS or community paediatrician ➢ **Return the *Shared Care Agreement Form*** (*below*) to the requesting specialist within 14 days of receipt. ➢ **Issue ongoing prescriptions** for lisdexamfetamine as per adjusting in line with specialist recommendations (continued prescribing is appropriate for patients attending specialist review). ➢ **Respond appropriately to resurgent or new symptoms or abnormal results,** communicating with secondary care where necessary. ➢ **Monitor for the risk of diversion, misuse and abuse of dexamfetamine or lisdexamfetamine** and alert the specialist

	➢ **Refer to specialist if patient's condition deteriorates** and if there are any side effects or concerns. ➢ **Oversee treatment cessation** on the advice of the specialist or request of the patient.
14. Responsibilities of all prescribers	➢ To monitor for the risk of diversion, misuse and abuse of lisdexamfetamine ➢ **Any suspected serious adverse reaction to an established drug should be reported to MHRA via the "yellow card scheme." http://yellowcard.mhra.gov.uk/**
15. Supporting documentation / information	*BNF* Section 4.4 CNS stimulants FDA Drug Safety Communication: Safety Review Update of Medications used to treat Attention-Deficit/Hyperactivity Disorder (ADHD) in children and young adults (November 2011): http://www.fda.gov/Drugs/DrugSafety/ucm277770.htm *"A large retrospective cohort study in children and young adults (aged 2-24 years) did not show an association between use of ADHD drugs and cardiovascular events, which include MI, stroke or sudden cardiac death. These study results were not consistent with the increase in sudden death estimated in a previous study, however a small to modest increase in risk cannot be excluded."*

GIG CYMRU NHS WALES | Bwrdd Iechyd Addysgu Powys / Powys Teaching Health Board

CONSULTANT REQUEST

To: Dr.

Your patient:	**NHS No. (10digit):**
was seen on:	
with a diagnosis of:	
I recommend that the following drug and dose is prescribed:	

This drug has been accepted as suitable for shared care by the *xxxxx*. I agree to the responsibilities set out in the protocol SCP No. xx (*copy attached*). This should be read in conjunction with the definition of shared care at: http://www.wales.nhs.uk/sites3/Documents/371/Doc%202%20Defining%20shared%20care.pdf

I am requesting your agreement to sharing the care of this patient. The preliminary tests set out in the agreement have been carried out. I am currently prescribing the stabilising treatment.

I would like you to undertake treatment from:
The initial treatment will be:
The baseline tests are:

If you undertake treatment I will reassess the patient in ____ weeks. You will be sent a written summary within 14 days. I will accept referral for reassessment at your request.

The medical staff of the department are available to give you advice between 9 – 5pm, Monday to Friday.

Consultant Name:	**Signature:**
Department:	
Hospital:	**Date:**
Contact Telephone Numbers:	

GP RESPONSE (*Please circle the appropriate number below detailing your response*)

1. I am willing to undertake shared care as set out in latest Powys Dexamfetamine and Lisdexamfetamine SCA for this patient.
2. I would like further information. Please contact me on: _____
3. I am unable to undertake shared care for this patient because: (*Please state reason*)

_____

G.P. Signature _____ Date _____

Practice Address/Stamp _____

PLEASE RETURN WHOLE COMPLETED FORM OR A COPY TO THE REQUESTING CONSULTANT WITHIN 14 days.
Thank you.