South East London Area Prescribing Committee
Formulary recommendation

Reference:	**005**
Intervention:	**Lisdexamfetamine dimesylate (Elvanse®▼) for the treatment of attention deficit/ hyperactivity disorder (ADHD) in children aged 6 years and over when response to previous methylphenidate is considered clinically inadequate** (Lisdexamfetamine is a pharmacologically inactive prodrug which is hydrolysed to dexamfetamine - a non-catecholamine sympathomimetic amines with CNS stimulant activity)
Date of Decision :	**October 2013**
Date of Issue:	**October 2013. Re-issued: September 2018. Revised in line with updated NICE guideline.**
Recommendation:	**Amber 3 - initiation and minimum 3 months supply by the specialist service.**
Further Information	• In line with the updated NICE guideline on the management of ADHD and the product licence, lisdexamfetamine is recommended in children aged 6 years and over 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. • Initiation is by specialists in childhood or/and adolescent behaviour disorder with transfer to primary care after at least 3 months if a patient responds to therapy and is stable, in line with the approved SEL shared care guideline. • Lisdexamfetamine is licensed for use in children aged 6 years and over with ADHD when response to previous methylphenidate treatment is considered clinically inadequate. Within the SPC it is stated that it may be appropriate to continue treatment into adulthood in adolescents whose symptoms persist into adulthood and who have shown clear benefit from treatment. • Lisdexamfetamine is taken once daily and thus avoids the problems associated with dexamfetamine which may need to be administered during school hours. • Lisdexamfetamine requires metabolic activation the manufacturer considers it to be relatively tamper proof and therefore to have a reduced abuse potential compared with dexamfetamine. Current interim advice from the Home Office and the Royal Pharmaceutical Society is that it should be treated as a Schedule 2 Controlled Drug the same as dexamfetamine and methylphenidate; atomoxetine is not treated as a Controlled Drug. • **Note:** The updated NICE guideline recommends that dexamfetamine is considered where ADHD symptoms are responding to lisdexamfetamine but patients cannot tolerate the longer effect profile. Refer also to the SEL shared care guideline.
Shared Care/Transfer of care document required:	Yes. NICE notes treatments could be used in children aged 5 years and over. However, the Committee has agreed that transfer of prescribing under shared care should only be for the licensed age ranges. Prescribing in under 6 years will be retained by the service.

Cost Impact for agreed patient group	As lisdexamfetamine is aimed at a relatively niche market and likely to displace medicines of similar cost (atomoxetine and dexamfetamine) it is unlikely to have a significant cost impact at a population level. The economic model submitted to the SMC estimated that on an individual patient level a switch from atomoxetine to lisdexamfetamine would increase medicine acquisition costs by £214 per year but that some of this increase would be offset by a reduction in administration and monitoring costs of £113 per year (not defined).
Usage Monitoring & Impact Assessment	**Trusts** • Submit usage/audit data on request to the APC. • Ensure shared care guideline is provided and adhered to **CCGs** • Epact data monitoring and exception reporting as needed of inappropriate use to Trust via medicines teams
Evidence reviewed	1. NICE ESNM19: Attention deficit hyperactivity disorder in children and young people: lisdexamfetamine dimesylate (May 2013). Accessed via http://publications.nice.org.uk/esnm19-attention-deficit-hyperactivity-disorder-in-children-and-young-people-lisdexamfetamine-esnm19 (last accessed 11/9/13) 2. Scottish Medicines Consortium. Lisdexamfetamine dimesylate (May 2013). Accessed via http://www.scottishmedicines.org.uk/files/advice/lisdexamfetamine_dimesylate__Elvanse__FINAL_April_2013_Amended_26.04.13_for_website.pdf (last accessed 11/9/13) 3. NICE. Clinical Guideline 72: Attention deficit hyperactivity disorder: Diagnosis and management of ADHD in children, young people and adults (2008). Accessed via http://publications.nice.org.uk/attention-deficit-hyperactivity-disorder-cg72 (last accessed 11/9/13) 4. Coghill D, Banaschewski T et al. European, randomized, phase 3 study of lisdexamfetamine dimesylate in children and adolescents with attention-deficit/hyperactivity disorder. European Neuropsychopharmacology 2013; doi:10.1016/j.euroneuro.2012.11.012 5. Dittmann RW, Cardo E et al. Efficacy and safety of lisdexamfetamine dimesylate and atomoxetine in the treatment of Attention-Deficit/Hyperactivity Disorder: a head-to-head, randomised, double blind, Phase IIIb study. CNS Drugs 2013 DOI 10.1007/s40263-013-0104-8 6. Summaries of Product Characteristics (SPCs) for various strengths of lisdexamfetamine (Elvanse®, Shire) available via: https://www.medicines.org.uk/emc/search?q=%22lisdexamfetamine+dimesylate%22 7. Updated NICE guideline 87 (NG87): Attention deficit hyperactivity disorder: diagnosis and management March 2018. Available at: https://www.nice.org.uk/guidance/ng87 (accessed 11/09/18)

NOTES:

a) Area Prescribing Committee recommendations, position statements and minutes are available publicly via the APC website.

b) This Area Prescribing Committee recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS.