South East London Area Prescribing Committee
Formulary recommendation

Reference	**046**
Intervention:	**Methylphenidate immediate release tablets, methylphenidate prolonged release tablets (as per shared care guidance) and dexamfetamine tablets for the treatment of idiopathic hypersomnia in adults**
Date of Decision	**January 2016.**
Date of Issue:	**February 2016. Re-issued: October 2018. Revised following development of shared care, re-categorised from red to amber 3.**
Recommendation:	**Amber 3 - initiation and minimum 6 months' supply by the specialist sleep service**
Further Information	• Methylphenidate prolonged release and dexamfetamine are supported for use in the treatment of idiopathic hypersomnia (IH). • Methylphenidate may be considered for patients with IH who: (i) Have an excessive daytime sleepiness score (ESS) of >12/24 **and** (ii) Have not responded to at least 3 months treatment with modafinil or have a contraindication to the use of modafinil • Dexamfetamine may be considered after methylphenidate for patients in whom methylphenidate is not effective or not appropriate. • When making its decision in February 2016, the Committee noted that in general there is a lack of randomised controlled trials in this area. In view of the specialist nature of the tertiary sleep service and that IH is a rare condition (1 in 20,000 prevalence), at the time the Committee agreed a time limited approval. This was to enable clinical leads within the sleep service to collect patient outcome data for presentation back to the Committee. • Data supporting appropriate use and safety were presented back to the Committee in July 2017 and the request to develop the shared care agreement was approved. • Lead clinicians should continue to collate observational outcome data on their experience with methylphenidate and dexamfetamine in this setting to contribute to the evidence base. • It should be noted that methylphenidate and dexamfetamine are not licensed for use in idiopathic hypersomnia. Informed consent should be gained from the patient before treatment is started. **Note:** Methylphenidate and dexamfetamine have a high risk of diversion and are a Schedule 2 controlled drugs. The potential for abuse, misuse or diversion should be considered prior to prescribing.
Shared Care/ Transfer of care required:	Yes

Cost Impact for agreed patient group	• Based on assumptions in the evidence evaluation, the cost impact of these medicines in IH is estimated to be approximately £1,500 to £10,000 per 100,000 population per year. • This equates in a total cost impact in SEL per year of between £27,000 to £180,000.
Usage Monitoring & Impact Assessment	Acute Trusts: • Submit usage/audit data on request to the APC. • Ensure shared care guideline is provided and adhered to.
	CCGs: • Monitor epact data • Monitor reports from GP practices where inappropriate transfer of prescribing to primary care is requested.
Evidence reviewed	**References (from evidence review)** 1. Khan Z, Trotti L. Central Disorders of Hypersomnolence – focus on the narcolepsies and idiopathic hypersomnia. Chest July 2015 148 (1) p262-273 2. American Academy of Sleep Medicine 2014. International classification of sleep disorders: diagnostic and coding manual 3rd edition. 3. Ohayon M, Priest R, Zulley J et al. Prevalence of narcolepsy symptomatology and diagnosis in the European general population. Neurology 2002, 58 (12) p1826-1833 4. Morgenthaler T, Kapur V, Brown T et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin – and American Academy of Sleep Medicine Report. Sleep 2007 30 (12) p1705-1711. 5. Golicki D, Bala M, Niewada M et al. Modafinil for narcolepsy: systematic review and meta-analysis. Medical Science Monitor 2010 16 (8) p177-186 6. Billard M, Sonka K. Idiopathic hypersomnia. Sleep Medicine Reviews 29 p23-33 7. Lavault S, Dauvilliers Y, Drouot X et al. Benefit and risk of modafinil as treatment for adults with idiopathic hypersomnia vs narcolepsy with cataplexy. Sleep Medicine 2011; 12 (6) p550-556. 8. Bastuji H, Jouvet M. Successful treatment of idiopathic hypersomnia and narcolepsy with modafinil. Progress in Neuropsychopharmacology and Biological Psychiatry 1988 12 p695-700 9. Anderson K, Pilsworth S, Sharples L et al. Idiopathic Hypersomnia: a study of 77 cases. Sleep 2007; 30 p1274-1281. 10. Ali M, Auger R, Slocumb N et al. Idiopathic Hypersomnia: clinical features and response to treatment. Journal of Clinical Sleep Medicine 2009 5 p562-568 11. European Medicines Agency 2011: Assessment report for modafinil containing medicinal products. Available online, accessed 03.01.2016 12. Summary of Product Characteristics: Modafinil Provigil tablets. Available online, accessed on 03.01.2016 13. Chang X, Lu X, Hong W. Stimulant drugs for narcolepsy in adults – protocol. Cochrane Collaboration November 2015. 14. Daly D, Yoss R. The treatment of narcolepsy with methylphendylpiperidylacetate: a preliminary report. Proceedings of the Staff Meetings of the Mayo Clinic 1956 31 p620-625 15. Yoss R Daly D. Treatment of narcolepsy with Ritalin. Neurology 1959: 9 p171-173 16. Parkes J, Baraister M, Marsden C et al. Natural history, symptoms and treatment of the narcoleptic syndrome. Acta Neurologica Scandivica 1975 52 p337-353 17. Shindler J, Schachter M, Brincat S et al. Amphetamine, mazindol, and fencamfemin in narcolepsy. British Medical Journal 1985 290 p1167-1170 18. Mitler M, Hajdukovic R, Erman M et al. Narcolepsy. Journal of Clinical Neurophysiology 1990 7 p93-118 19. Bassetti C, Aldrich M. Idiopathic Hypersomnia: a series of 42 patients. Brain 1997 120 p1423-1435 20. Committee for Medicinal Products for Human Use November 2015. Summary of Opinion – Wakix (pitolisant). Available online at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002616/smops/Positive/human_smop_000902.jsp&mid=WC0b01ac058001d127 <accessed on 02.01/2016> 21. Wozniak D, Quinnell T. Unmet needs of patients with narcolepsy: perspectives on emerging treatment options. Nature and Science of Sleep 2015 7 p51-61 22. Pliska S, Matthews T, Braslow K et al. Comparative effects of methylphenidate and mixed salts amphetamine on height and weight in children with attention-deficit hyperactivity disorder. Journal of the American Academy of Child and Adolescent Psychiatry 2006 45 p520-526 23. Summary of Product Characteristics: Amfexa 5mg tablets. Available online, accessed 04.01.2016 24. Summary of Product Characteristics: Ritalin. Available online, accessed 01.01.2016 25. Klein-Schwartz W. Abuse and toxicity of methylphenidate. Current Opinions in Pediatrics 2002 14 p219-223 26. Guilleminault C. Amphetamines and narcolepsy: use of the Stanford database. Sleep 1993 16 (3) p199-201

NOTES:

a) Area Prescribing Committee recommendations 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.**