South East London Area Prescribing Committee
Formulary recommendation

Reference	**089**
Intervention:	**Specific agents (modified release melatonin/clonazepam/ diazepam/zopiclone/clomipramine/imipramine/fluoxetine/sertraline) for the management of non-REM parasomnia in adults** (Modified release melatonin/clonazepam/ diazepam/zopiclone are sedative agents; clomipramine and imipramine are tricyclic antdepressants; fluoxetine and sertraline are SSRI antidepressants)
Date of Decision	**July 2018**
Date of Issue:	**August 2018**
Recommendation:	**Amber 2 – initiation and minimum 3 months supply by the specialist sleep service**
Further Information	• Modified release melatonin/clonazepam/ diazepam/zopiclone/ imipramine/ clomipramine/fluoxetine/sertraline are accepted for use in South East London in line with the local pathway as treatment options for the management of non-REM parasomnia in adults. • Modified release melatonin is the **first line** treatment option and administered at a dose of 0.5mg to 6mg at night. • Clonazepam is a **second line** option (at a dose of 0.25mg to 4mg at night) where there is no significant improvement or there is an adverse reaction to melatonin. Note: There may be circumstances where clonazepam is considered a first line option where parasomnia behaviours place the patient or others at risk of harm. • **Third line** monotherapy options include: Hypnotics (diazepam and zopiclone), tricyclic antidepressants (clomipramine and imipramine) and the SSRI antidepressants, fluoxetine and sertraline. Refer to the pathway for dosing information. • The decision on choice of third line agent will be made by the sleep specialist taking into account individual patient factors, such as symptoms. • Treatment will be initiated and monitored by the sleep service. The service will regularly review patients for ongoing effectiveness of treatment. • The sleep service will prescribe ongoing supply for a **minimum of 3 months**. • Prescribing will only be transferred to primary care once the therapy is confirmed as effective, the patient is on a stable dose and has been confirmed to be tolerating the medication. • The sleep service will provide the patient's GP with information for GPs and pharmacists and sleep hygiene information. • It should be noted that these agents are not licensed for use non REM sleep parasomnia. Informed consent should be gained from the patient before treatment is started. • Clonazepam, diazepam and zopiclone are schedule 4 (part 1) controlled drugs. Prescribers should be aware of the risks associated with these agents, including falls, cognitive impairment, dependence and withdrawal symptoms. These risks will be considered by the sleep specialist team before these agents are initiated for non-REM sleep disorder.
Shared Care/ Transfer of care required:	No - individual management plan to be in place, e.g. detailed clinic letter and supporting resources.

Cost Impact for agreed patient group	• The formulary submission suggests that 35 patients might be suitable for clonazepam, 15 for melatonin, 10 for diazepam, 15 for fluoxetine or sertraline, 5 for imipramine or clomipramine, and 5-10 for zopiclone per annum at the sleep centre, and that 50% would be expected to come from SE London. • The estimated cost of these treatments for SE London is therefore approximately £4,650 per annum.
Usage Monitoring & Impact Assessment	• Sleep centre to monitor use and submit usage data and audit reports (against this recommendation and the treatment pathway) upon request to the APC.
	• CCGs to monitor ePACT data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	**References (from evidence evaluation)** 1. Fantini M, Puligheddu M, Cicolin A. Sleep and Violence. Current Treatment Options in Neurology 2012 14 p 438–450. 2. Fleetham J, Fleming J. Parasomnias. Canadian Medical Association Journal 2014 186 (8) E273-280 3. Galbiati A, Manni R, Terzaghi M et al. Disorders of arousal. Curr Sleep Medicine Rep (2016) 2: p53–63 4. Gupta M, Aneja S, Kohli K. Add-on melatonin improves sleep behaviour in children with epilepsy: randomized, double-blind, placebo-controlled trial. J Child Neurol 2005;20:112–115 5. Gupta M, Gupta YK, Aneja S, et al. Effects of add-on melatonin on sleep in epileptic children on carbamazepine monotherapy: a randomized placebo controlled trial. Sleep Biol Rhythms 2004;2:215–219 6. Schenck CH, Mahowald MW. Long-term, nightly benzodiazepine treatment of injurious parasomnias and other disorders of disrupted nocturnal sleep in 170 adults. Am J Med. 1996;100 p333–7 7. Reid WH, Haffke EA, Chu CC. Diazepam in intractable sleepwalking: a pilot study. Hillside J Clin Psychiatry. 1984;6 p49–55. 8. Muza R, Lawrence M, Drakatos D. The reality of sexsomnia. Current Opinion in Pulmonary Medicine; Oct 2016; vol. 22 (no. 6); p. 576-582 9. Cooper AJ. Treatment of coexistent night-terrors and somnambulism in adults with imipramine and diazepam. J Clin Psychiatry. 1987; 48: p209–10. 10. Attarian H, Zhu L. Treatment options for disorders of arousal: a case series. Int J Neurosci. 2013;123 p623–5 11. Froelich A, Lehnkuhl G. Successful treatment of severe parasomnias with paroxetine in a 12-year-old boy. Int J Psychiatry Clin Pract. 2001 5 (3) p215-8 12. The Drug Tariff, April 2018. Available online at: https://www.nhsbsa.nhs.uk/pharmacies-gppractices-and-appliance-contractors/drug-tariff (accessed 08/04/2018)

NOTES:

a) Area Prescribing Committee recommendations and minutes are available publicly on member CCG websites.

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.