South East London Integrated Medicines Optimisation Committee
(SEL IMOC, formerly the SEL Area Prescribing Committee)
Formulary recommendation

Reference	**118**
Intervention:	**Melatonin 1mg and 5mg prolonged release tablets (Slenyto®) for managing insomnia in children and adolescents (aged 2 years to 18 years)** (Melatonin is a hormone released by the pineal gland in the brain that regulates the sleep–wake cycle)
Date of Decision:	**October 2020**
Date of Issue:	**November 2020**
Recommendation:	**Amber 3 – initiation and supply by specialist paediatric teams for a minimum of 2 months. GPs may be asked to take on prescribing after this time if the patient's condition is stable.**
Further Information:	· Melatonin 1mg and 5mg prolonged release tablets (Slenyto®) are accepted for use in SEL as **an option** for the management of insomnia in children and adolescents in line with the medicine's licensed indication, i.e. *The treatment of insomnia in children and adolescents aged 2-18 years with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient.* · Treatment and ongoing review will follow the local melatonin pathway, which describes the place in therapy of different melatonin products. · In line with the local melatonin pathway, behavioural interventions will have been trialled for at least 3 months before treatment with a melatonin product is considered. · Within the local melatonin pathway, Slenyto® is restricted as a treatment option for the **licensed cohort** of patients only. · Patients who are stable on their existing melatonin treatment should not be switched to Slenyto®. · To simplify product choice and the prescribing process, there are three preferred melatonin products in SEL and these should be prescribed by **brand.** Refer to the local melatonin pathway for further information. · There are limited data on the long-term use of melatonin generally and in view of this, patients will undergo regular review by the specialist paediatric team (6 monthly) and treatment breaks will be considered in line with the local melatonin pathway. · Behavioural measures will form part of the ongoing treatment plan for paediatric and adolescent patients with insomnia. · Melatonin products for sleep disorders in paediatrics will be initiated and prescribed by the specialist paediatric team for at least the first two months before prescribing can be transferred to the GP, in line with the shared care guideline.
Shared Care/ Transfer of care required:	Yes.
Cost Impact for agreed patient group	· Local paediatric expert's estimate that 25 patients per 100,000 population per year would require melatonin, out of these 10 patients per 100,000 would be initiated on Slenyto® for the treatment of insomnia in children and adolescents in line with the licence. Potentially ~50% of the existing SEL paediatric caseload is suitable for switching over to Slenyto® (~12 patients per 100,000 population). · The use of Slenyto® in these patients would result in an additional cost of ~£17,000 per 100,000 population per year (or ~£328,000 for SEL). · The additional cost is likely to be lower as local experts believe the switch rate may be lower.

Usage Monitoring & Impact Assessment	**Trusts:** · Monitor use and submit usage data and audit reports (against this recommendation and the pathway) upon request to the SEL IMOC.
	SEL CCG Borough Medicines Teams: · Monitor EPACT 2 data · Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed:	**References (from evidence evaluation)** 1. Heussler H. Management of sleep disoders in neurodevelopmental disorders and genetic syndromes. Curr Opin Psychiatry. 2016 Mar;29(2):138-43. 2. Autism spectrum disorder in under 19s: support and management (CG170). National Institute for Health and Care Excellence 2013. 3. SIGN 145 Assessment, diagnosis and interventions for autism spectrum disorders 2016 4. Slenyto. Summary of Product Characteristics. Available online at: https://www.medicines.org.uk/emc/product/10023/smpc (accessed 04/10/2019). 5. Gringras P, Nir T, Breddy J et al. Efficacy and Safety of Pediatric Prolonged Release Melatonin for Insomnia in Children with Autism Spectrum Disorder. Journal of the American Academy of Child and Adolescent Psychiatry 2017 56 (11) p948-957. 6. Maras A, Schroder C, Malow B et al. Long-Term Efficacy and Safety of Pediatric Prolonged-Release Melatonin for Insomnia in Children with Autism Spectrum Disorder. Journal of Child and Adolescent Psychology 2018 28 (10) p699-710. 7. Schroder C, Malow B, Maras A et al. Pediatric Prolonged Release Melatonin for Sleep in Children with Autism Spectrum Disorder: Impact on Child Behavior and Caregiver's Quality of Life. Journal of Autism and Developmental Disorders 2019 49 p3218-3230. 8. Gringras P, Gamble C, Jones A et al. Melatonin for sleep problems in children with neurodevelopmental disorders: randomised double masked placebo controlled trial. British Medical Journal 2012 345 doi 10.1136/bmj.e6664. 9. Cortesi F, Giannotti F, Sebastiani T et al. Controlled-release melatonin, singly combined with cognitive behavioural therapy, for persistent insomnia in children with autism spectrum disorders: a randomized placebo-controlled trial. Journal of Sleep Research 2012 21 p700-709. 10. Slenyto. Public Assessment Report. EMA 2018. 11. PresQIPP July 2019. Newly licensed melatonin preparations (subscription only). 12. Melatonin 1 mg and 5 mg prolonged release tablets (Slenyto). SMC 2168.

NOTES:

a) SEL IMOC recommendations and minutes are available publicly via the website.

b) This SEL IMOC 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