South East London Area Prescribing Committee
Formulary recommendation

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| Intervention: | Melatonin (2mg modified release) for the management of specific headache disorders (all off-label use)  
(Melatonin is a naturally occurring hormone produced by the pineal gland and is structurally related to serotonin) |
| Date of Decision | June 2019 |
| Date of Issue: | July 2019 |
| Recommendation: | RED – Prescribing and supply by hospital only |

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<th>Further Information</th>
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| • Melatonin 2mg modified release tablets are accepted for use in SEL for the management of the following headache disorders:  
  - Cluster headache  
  - Migraine  
  - Hypnic headache  
  - Hemicrania continua  
  - Tension-type headache  
  - Primary stabbing headache  
  - Secondary short-lasting unilateral neuralgiform headache with conjunctival injection and tearing (SUNCT)  
• The use of melatonin is restricted to a last line option after all other treatments have been trialled or considered but are not effective, not tolerated or contra-indicated. Patient factors (such as co-morbidities and other medicines the patient is taking) will also be considered by the initiating specialist.  
• The dose range for melatonin in this setting is 2mg-10mg per day depending on the type of headache disorder. In general, lower doses (2mg per day) are used in migraine and tension-type headache. The higher doses are reserved for cluster headache.  
• For migraine, in line with the available evidence, the use of melatonin is only supported as monotherapy.  
• Patients will be reviewed by the service at 6 months, which will include assessment of the severity, frequency and duration of attacks (using headache diaries and quality of life scores), symptom control and tolerability.  
• Melatonin is not licensed for use in these headache disorders. Informed consent should be gained from the patient before treatment is started.  
• A pathway for the management of headache disorders will be developed to outline the place in therapy of the various treatment options. Until the pathway is agreed, melatonin will be categorised as red across SEL. Funding will need to be confirmed at individual Trust level as melatonin in this setting will be prescribed and supplied by the hospital.  

| Shared Care/ Transfer of care required: | N/A |
| Cost Impact for agreed patient group |
| • The formulary application estimates that 70 patients would be suitable for treatment across KCH and GSTT.  
• If 50 of those were from SE London, this would equate to additional costs of between £9,250 to £46,500 per annum for SE London depending on the dose.  
• These costs are likely to be an overestimate as there is already some prescribing of melatonin occurring in this setting. |

| Usage Monitoring & Impact Assessment | Acute Trusts:  
• Monitor use and report back to APC when required.  
• Audit use upon request to ensure use is in line with this recommendation. |
Usage Monitoring & Impact Assessment (cont’d)

CCGs:
- Monitor Epact 2 data.
- Monitor exception reports from GPs if inappropriate prescribing requests are made to primary care.

Evidence reviewed

References (from evidence evaluation)

8. Circadin. SPC. Available online here (accessed 29/10/2018)
22. Spears R. Hemicrania continua: a case in which a patient experienced complete relief with melatonin. Headache 2006 55 p244-252
23. Hollingworth M, Young T et al. Melatonin responsive hemicranias continua in which indomethacin was associated with contralateral headache. Headache 2014 54 p916-919

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.

South East London Area Prescribing Committee. A partnership between NHS organisations in South East London: Bexley, Bromley, Greenwich, Lambeth, Lewisham and Southwark Clinical Commissioning Groups (CCGs) and GSTFT/KCH /SLAM/Oxleas NHS Foundation Trusts/Lewisham & Greenwich NHS Trust