POLICY FOR MELATONIN PRESCRIBING IN ADULTS OVER 18 YEARS

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1. INTRODUCTION

Melatonin is a naturally occurring hormone produced by the pineal gland in the brain. It is involved in coordinating the body's sleep-wake cycle and helping to regulate sleep.1 Risks associated with the long-term use of benzodiazepine and 'Z-drug' hypnotics have been well recognised for many years. Recent data suggests similar safety concerns with melatonin. These risks include falls, accidents, cognitive impairment, dependence and withdrawal symptoms, and an increased risk of dementia.2 Melatonin treatment is intended to be short-term.1-3 Patients should be reviewed for the continued need for melatonin.

The SPC for Circadin® states that treatment may be continued for up to 13 weeks.3 Any patients receiving Circadin® for more than 13 weeks should have their treatment reviewed.

1.1 Purpose

- To ensure that melatonin prescribing is safe and clinically appropriate for the age of the patient, and the indication prescribed for is evidence based
- To ensure that melatonin treatment is reviewed within recommended intervals and that duration is within licensed recommendations
- To ensure that melatonin formulations and doses are optimised for the individual patient to avoid unnecessary costs

1.2 Scope

All prescribers who work within or contracted to Manx Care.

2. POLICY/PROCEDURE/GUIDELINES

A licensed melatonin preparation for use in adults 55 years or over has been available for some time. Circadin (melatonin) prolonged-release (P/R) 2mg tablets are licensed in patients who are aged 55 or over for the short-term treatment of primary insomnia characterised by poor quality of sleep. The dose may be continued for up to 13 weeks.

The annual spend in England and Wales on all melatonin preparations (ePACT2 Feb-Apr 19) is £30 million; £7.8 million of this is for unlicensed melatonin preparations.

The current annual spend in the Isle of Man for all melatonin preparations (adult & children) is £130,000. Melatonin appropriateness for under 18's will be undertaken in a separate audit
The first melatonin preparations licensed for the short-term treatment of jet lag in adults (melatonin 3mg tablets, melatonin 1mg/ml oral solution) are now available.

Consideration should be given to the use in preference to unlicensed melatonin preparations. There may be significant cost pressures if they are introduced without consideration given to medicines optimisation. Cost savings are possible if melatonin formulations and doses are optimised for the individual patient.

There is insufficient evidence to support the prescribing of melatonin for sleep disorders associated with jet lag or shift work. Adults continuing on melatonin treatment beyond licensed recommendations need to be reviewed as little is known about the long-term effects of melatonin.

Melatonin is included in the general safety warnings on hypnotics including the risk of falls and fracture, dependence and withdrawal symptoms.

2.1 Current patients

All patients currently prescribed melatonin, both licensed and unlicensed, should be reviewed. Patients who have a learning disability and behavioural challenges (where sleep hygiene measures have been insufficient) can have melatonin prescribed up to 10mg per day all other criteria would still apply. Treatment duration is intended to be short and so it is important that the continued need for treatment and monitoring of adverse effects are reviewed at appropriate intervals.

Treatment should be stopped in discussion with the individual if it is ineffective, producing adverse effects or no longer required.

Patients who fail to attend their appointments should not have prescriptions issued until reviewed.

2.2 New patients

Before starting melatonin treatment consider the use of a sleep diary (https://www.nhs.uk/livewell/insomnia/documents/sleepdiary.pdf [4]); the use of a

sleep diary is crucial in establishing the sleep routine and in determining the pattern of sleep difficulties.

Patients should keep a sleep diary both prior to commencing medication and once medication has started. Review of the diary should occur at follow-up appointments to assist with decisions regarding dosage and continuation. Effectiveness of interventions should be documented in the clinical notes at review.

Signposting to the relevant sleep management websites for Information regarding sleep is essential, patients should be provided with sleep information and advice.

Consider initiating treatment with melatonin only when non-pharmacological measures have been tried and failed.

3. SUMMARY

- Melatonin is widely used and yet it has narrow licensed uses.
- Melatonin has been included in warnings on adverse effects with other hypnotics.
- Treatment duration is intended to be short and so it is important that patients continued need for treatment is reviewed at appropriate intervals.
- Treatment should be stopped in discussion with the individual if it is ineffective, producing adverse effects or no longer required.
- Melatonin 3mg tablets and 1mg/ml oral solution (Colonis Pharma Ltd) were recently licensed for the short-term treatment of jet lag in adults.
- NHS prescriptions for melatonin should not be issued for anticipatory use for jet lag.
- Prescribers should review the use of unlicensed melatonin preparations with a view to switching patients to a cost-effective licensed alternative suitable for the individual patient.
- Melatonin doses need to be optimised to manage any potential cost increases when switching melatonin preparations.

4. REFERENCES AND/OR RESOURCES

1 European Medicines Agency. Committee for Medicinal Products for Human Use (CHMP) Slenyto®
Assessment Report, 26 July 2018. Available at: https://www.ema.europa.eu/en/documents/assessment-report/slenyto-epar-public-assessment-report_en.pdf Accessed 22/03/2019

2 MHRA Guidance Note 14. The supply of unlicensed medicinal products ("specials"). 2014. Available at:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf Accessed 22/03/2019

3 Summary of Product Characteristics. Circadin®. Flynn Pharma Limited. Available at*: www.medicines.org.uk Accessed 22/03/2019*

4 Kevin Morgan, Beverley David, Claire Gascoigne (2007). Clinical Sleep Research Unit Loughborough University Available at *https://www.nhs.uk/livewell/insomnia/documents/sleepdiary.pdf Accessed on 15th June 2022*