NHS
Suffolk and
North East Essex

Prescribing of Melatonin in Primary Care Settings

The Suffolk and North East Essex Integrated Care Board (SNEE ICB) supports the prescribing of melatonin in primary care settings for sleep disorders in children and adolescents secondary to neurological/neurodevelopmental disorders, including attention deficit hyperactivity disorder (ADHD), autism, and visual impairment only.

The ICB does not support prescribing of melatonin for any other indication.

Melatonin should not be initiated in patients aged 18 years and over. However, treatment may be continued in patients aged 18 years and over if initiated when the patient was a child.

Note: This is provided that the continued need for treatment is reviewed and as a minimum an annual drug holiday is introduced.

Melatonin carries a 'green' traffic light status locally, i.e., prescribing must only be undertaken following patient consultation with, and on the recommendation of, a specialist with the appropriate expertise.

The following guidance seeks to ensure that prescribing of melatonin in primary care settings is safe, appropriate, includes regular review, and supports deprescribing when appropriate. The content is largely based on information provided by PrescQIPP in its bulletin no. 318 'Melatonin' published in January 2023.

General recommendations – applicable to all patients

1. Melatonin should only be prescribed on the recommendation of a specialist and always alongside non-pharmacological interventions.
2. An adequate baseline sleep diary should be obtained before any trial of melatonin, and patients should be advised to follow sleep hygiene measures and to maintain the sleep diary throughout treatment if practicable.
    - Useful resources that can be shared with patients, or their parents or carers can be found in Appendix 1 of this document.
    - A daily sleep diary template can be accessed via this link: https://www.nhs.uk/livewell/insomnia/documents/sleepdiary.pdf
3. All patients prescribed melatonin should be reviewed after three months, and melatonin deprescribed if there is no clinically relevant treatment effect observed. Treatment can safely be stopped abruptly.
4. All patients should undergo regular, two-week 'drug holidays' to assess their need for ongoing treatment (see sub section below for further information). If sleep improvements are maintained without melatonin, therapy should be stopped.
5. Most children and young people do not require long term treatment with melatonin. Attempts to discontinue treatment should be made regularly, e.g., at least once per year. Once a predictable sleep cycle has been established, consider stopping treatment or tapering off gradually, depending on discussion with the patient and/or caregiver.
6. A cost-effective, licensed preparation should be selected where possible:
    - Where immediate-release melatonin is indicated, the licensed tablets (crushed if needed) are more cost-effective than the capsules and liquid.

- Where modified-release melatonin is indicated, the 2mg prolonged release tablets are the least costly.

7. Patients with swallowing difficulties:
   - 1mg to 5mg immediate-release melatonin tablets (Adaflex®) can be crushed and mixed with water directly before administration (licensed for insomnia in children and adolescents aged 6-17 years with ADHD).

     Note: This is a more cost-effective choice than the solution.
   - Alternatively, melatonin is available as a 1mg/ml oral solution (licensed for sleep onset insomnia in children and adolescents aged 6–17 years with ADHD).
8. For patients prescribed unlicensed or 'off-label' melatonin, the prescriber should be satisfied that there is no suitably licensed medicine that will meet the patient's need. Patients, or their parents or carers, must be given sufficient information about the unlicensed medicines proposed, to allow them to make an informed decision.

   Further information on the range of products and formulations available, including their licensing conditions, can be found in:
   - The BNF for Children: Melatonin | Drugs | BNFC | NICE
   - The Electronic Medicines Compendium (emc):

Drug holidays and deprescribing

To ascertain whether there is an ongoing need for melatonin, regular drug holidays should form part of the patient's treatment plan.

Drug holidays should be considered three months post initiation and six-monthly thereafter.

Treatment can safely be stopped abruptly and should be stopped for two weeks.

A patient guide to undertaking a drug holiday is accessible via this link: Melatonin and Drug Holidays: Information for Patients

If sleep improvements are maintained without melatonin, therapy should be stopped.

If sleep deteriorates and continues to be an issue, melatonin should be re-instated. The patient should be advised to reintroduce melatonin at a low dose then, and only if necessary, gradually titrate back up to the original dose where sleep improved. Ongoing drug holidays should be considered at annual review.

If there is a consistent correlation of sleep deterioration during the drug holiday, patients should be advised to continue without a break unless they are suspected to be a poor metaboliser of melatonin (see below).

Note on poor metabolisers:

Poor metabolisers of melatonin may find that melatonin efficacy reduces over time as melatonin accumulates in the plasma and this leads to an absent peak concentration at bedtime. This is identified through clinical history - patients may report an initial benefit with melatonin and then ineffectiveness.

To see a continued effect with melatonin, these patients may need regular two-week washout periods. A drug holiday when the effect has waned will facilitate washout and patients often see a benefit after recommencement.

Cautions, side effects, and drug interactions

Treatment with melatonin is not recommended during pregnancy or in women of childbearing potential not using contraceptives.

Melatonin is not recommended during breastfeeding.

Common side effects of melatonin treatment include arthralgia, increased risk of infection, and pain. A full list of side effects is accessible via this link: Melatonin | Drugs | BNF | NICE

A full list of drug interactions is accessible via this link: Melatonin | Interactions | BNF | NICE

Note: Melatonin may cause drowsiness and may decrease alertness for several hours, therefore it is not recommended prior to driving and using machines.

Information relevant to specific disorders

1. Sleep disorders and attention deficit hyperactivity disorder (ADHD)

Specialist involvement: Melatonin should not be routinely prescribed for patients with ADHD. It should only be prescribed on specialist recommendation and if other treatments are ineffective/unsuitable, in line with the manufacturer recommendations.

Prescribing: Immediate-release melatonin (not all brands) is licensed for the treatment of insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient.

Note: Prolonged-release melatonin is not licensed for this indication.

2. Autism Spectrum Disorder (ASD)

There is evidence to support the use of melatonin in children and adolescents with a variety of neurodevelopmental disorders, and children with ASD or neurodevelopmental disabilities caused by Smith-Magenis syndrome.

The NICE clinical guideline on ASD in under 19s (CG170) recommends that a pharmacological intervention to aid sleep is only recommended for use in ASD in under 19s if sleep problems persist despite following a sleep plan and if sleep problems are having a negative impact on the child or young person and their family or carers.

Specialist involvement: Where melatonin is being considered, and before treatment is started, all patients under the age of 19 with ASD should have a consultation with a specialist with expertise in the management of autism or paediatric sleep medicine.

Prescribing: The Slenyto® brand of prolonged-release melatonin is licensed for the treatment of insomnia in children and adolescents aged 2-18 with ASD and/or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient.

Note: The NICE clinical guideline on ASD diagnosis and management in adults (CG142) does not discuss insomnia or sleep disorders.

3. Challenging behaviour and learning disabilities

The NICE guideline on prevention and interventions for people with learning disabilities whose behaviour challenges (NG11) states that medication should not be offered to aid sleep unless the sleep problem persists after a behavioural intervention.

Specialist involvement: Where melatonin is being considered, and before treatment is started, all patients with challenging behaviour and learning disabilities should have a consultation with a specialist with expertise in melatonin use in people with a learning disability.

Note: If medication is needed to aid sleep, NICE recommends that melatonin should be considered. This is an off-label use.

Appendix 1

The following resources may be helpful in supporting healthy sleep patterns and are appropriate for sharing with patients or their parents or carers:

- West Suffolk NHS Foundation Trust: Sleep - a guide for school aged children
- NHS: Sleep problems in young children
- Great Ormond Street Hospital: Sleep Hygiene
- The Sleep Charity: Understanding Your Sleep
- Cerebra: Sleep Advice Service
- Contact: Helping you and your child sleep
- Mencap: Sleeping tips