Insomnia in Adults

In primary care, when diagnosing and managing insomnia please refer to

NICE CKS: Insomnia

If sleep difficulties are related to low level anxiety or depression and sleep hygiene measures have proven ineffective patients can also self-refer to the NHS Talking Therapies service (in Blackpool, Healthier Minds).

If the NICE CKS recommends pharmacological measures for a patient's condition please also refer to Lancashire and South Cumbria medicines formulary.

Prescribing of melatonin in L&SC is restricted to indications approved by LSCMMG.

For additional supporting information on the prescribing of melatonin please see Appendix 1.

For 'Melatonin Pathway (Children)' please click here.

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Appendix 1. Melatonin supporting information

LSCMMG approved indications for melatonin in adults, where non-pharmacological methods are insufficient

- **Sleep problems in adults with learning disabilities**
  Consider behavioural interventions for sleep problems in adults with a learning disability and behaviour that challenges.
  Do not offer medication to aid sleep unless the sleep problem persists after a behavioural intervention, and then only after consultation with a psychiatrist with expertise in its use in people with a learning disability. (NG11)
  In practice, this may include other prescribers within the specialist team (e.g. specialist nurses).
- **Sleep problems in adults with ADHD**
  Ensure that people with ADHD have a comprehensive, holistic shared treatment plan that takes into account the severity of ADHD symptoms and impairment, and how these affect or may affect everyday life (including sleep). (NG87)
  In practice, sleep related symptoms may be managed by prescribers within the specialist team (e.g. specialist nurses).
- **Adults with sleep disorders who are totally blind**
  Limited evidence suggests that melatonin might improve total night sleep duration, and reduce the amount of time spent awake after falling asleep in adults with sleep disorders who are totally blind. (ES38)
- **Sleep disturbances in Cerebral palsy in under 25s**
  Manage treatable causes of sleep disturbances that are identified in young people with cerebral palsy. If no treatable cause is found, consider a trial of melatonin, particularly for problems with falling asleep. (NG62)
- **Rapid Eye Movement (REM) Sleep Behaviour Disorder (RBD) in Parkinson's Disease and Lewy Body Dementia**
  Consider clonazepam or melatonin to treat rapid eye movement sleep behaviour disorder if a medicines review has addressed possible pharmacological causes. (NG71)
- **Sleep problems in adults with complex neurodevelopmental disorders that the specialist considers eligible**
- **Young people on established melatonin therapy who are transitioning into adult services**

All other indications should be considered as RAG rated 'Do Not Prescribe'.

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Prescription supporting information for melatonin

Treatment aims and target symptoms must be documented in the patients notes.

Frequency Once daily

Route and formulation

First line – Melatonin 2mg modified-release tablets – Oral, with or after food, 1-2 hours before bedtime.

Second line – Melatonin Immediate release formulations – Oral, on an empty stomach, 2 hours before or 2 hours after food (ideally at least 3 hours after food in those with significantly impaired glucose tolerance or diabetes)—intake with carbohydrate-rich meals may impair blood glucose control.

Options for patients with swallowing difficulties

Circadin brand 2mg MR tablets

- Circadin® 2mg MR tablet may be halved using a tablet cutter, and it will retain its slow-release characteristics to some extent (unlicensed).
- For patients with difficulties swallowing, the tablet can be crushed to a fine powder and mixed with water or jam. Use a small amount of food to ensure that the full dose is taken. Prescribers should be aware that once crushed the tablet will not retain its slow release characteristics (unlicensed).
- Circadin MR tablet is not licensed to be given through enteral feeding tubes. However, the manufacturers state that if necessary it can be crushed (note - this would change it from a modified-release tablet to an immediate-release one) and mixed in 15-30mL of water for administration through enteral feeding tubes. The tube should be flushed well after administration (unlicensed).

Adaflex tablets

The tablet can be crushed and mixed with water directly before the administration (licensed).

Melatonin 1mg/mL oral solution (Ceyesto)

Melatonin oral solution should be reserved for use in patients unable to use other oral formulations.
Can be administered via silicone gastric, duodenal or nasal feeding tubes.
Melatonin liquid manufactured by Colonis Pharma Ltd should not be prescribed.

Cautions

Avoid in patients with autoimmune disease.
Risk of increased seizure frequency in patients with susceptibility to seizures.

Information for patients and carers

Patients and/or carers should be informed of any off-label or unlicensed use of prescribed medication, in line with the prescriber's professional guidance.

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For the most up to date information on cautions, contra-indications, side effects and interactions, please refer to the product SPC.

Melatonin review and patient follow up

3 - 6 months Review should take place 3 - 6 months after initiation, by the team who initiated the melatonin.

Review may be in person, via telephone or video call.

If the specialist team, together with the patient and/or carer considers there to have been a satisfactory response to treatment in terms of:

- An increase in sleep duration by 60 minutes or more, or
- A significant reduction in the number of night time waking episodes, or
- A consistent shift in sleep pattern towards earlier settling to sleep, or
- The ability to wake in the morning in order to get to work on time, or
- A reported improvement in daytime functioning,

then treatment may continue. Refer to the treatment aims and target symptoms from the initial assessment.

Once a stable dose is reached then prescriptions can be issued in primary care (RAG Amber 0).

In patients where a response is considered unsatisfactory, treatment should be stopped immediately.

6 - 12 months Patient's should have their melatonin therapy reviewed at least annually to assess response.

This review can be conducted in primary care or by the patient's specialist team who initiated therapy.

Refer to the documented treatment aims and target symptoms from previous assessments.

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The date and outcome of the review should be clearly documented on the patient's EMIS record and communicated between the patient's specialist and their GP.

Drug Holiday

The review should include a melatonin 'drug holiday'; melatonin should be withdrawn and any changes in sleeping pattern observed. Withdrawal can be abrupt or gradual and may be conducted in conjunction with a sleep diary to monitor for any significant deterioration in sleep pattern.

Clinically significant deterioration is considered as:

- A decrease in sleep duration of 60 minutes or more
- A significant increase in the number of night time waking episodes
- A consistent shift in sleep patterns towards longer periods to get settled to sleep
- An inability to wake in the morning to get to work on time
- Reported deterioration in daytime functioning

Rebound worsening in sleep pattern may occur initially but this may improve over time.

If after 7-14 days sleep has deteriorated significantly melatonin can be restarted at the lowest effective dosage for another 6 – 12 months alongside sleep hygiene measures.

Melatonin treatment should not be considered as indefinite. The annual review should determine if treatment remains efficacious for the individual and if the patient still requires melatonin therapy or if sleep hygiene measures are now sufficient.

A pragmatic approach should be used for young people who are transitioning into adult services. Whilst any intervention which risks causing a deterioration in the patient's clinical picture would be counterproductive, revisiting sleep hygiene measures and consideration of new services available to support the young adult is encouraged. A sleep diary may also be beneficial at this stage to ascertain if any ongoing melatonin prescriptions are still conferring a clinically significant benefit.

References

National Institute for Health and Care Excellence, 'CKS Insomnia', 2025

National Institute for Health and Care Excellence, 'Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges (NG11)', 2015

National Institute for Health and Care Excellence, 'Cerebral palsy in under 25s: assessment and management', 2017

National Institute for Health and Care Excellence, 'Attention deficit hyperactivity disorder: diagnosis and management (NG87)', 2018

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BNF, ‘Melatonin’, 2023

EMC, ‘Summary of product characteristics’, 2024

Version Control

Version Number	Date	Amendments Made	Author
Version 1		New document	JG

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