Melatonin Pathway (Children)

For melatonin prescribing guidance in adults please click here

Child presents in primary care with sleeping difficulties.

Step 1. Sleep hygiene and signposting

Consider causes of sleeping difficulties

Consider if there are **medical**, **medication** or **social** causes of their sleep difficulties.
If so, review these alongside advising sleep hygiene measures.

Sleep hygiene

If the patient is able to trial sleep hygiene measures, then provide the patient with information on what this means and set an agreed time for the next review (**Step 2**).

Sleep hygiene measures

- Create a cool, quiet, dark sleeping environment
- Establish a bed time routine (e.g. bath time, brush teeth, pyjamas)
- Try to maintain a consistent bedtime and wake time, even at weekends
- Discuss appropriate meal timing and physical activity routines
- Try to relax before going to bed
    - Avoid screen time (TV, phone, computer) for at least 2 hours before bed time
    - Avoid caffeine at least three hours before planned sleep time
    - Emphasise that the child's bed should be for sleep only and not for stimulating activities such as watching TV
    - Discuss self-soothing techniques and relaxation techniques

Support

Children under 5 may be referred to their health visitor who can arrange a home visit or conversation to support families with sleep hygiene measures.

Children of school age can be referred to the school nurse (where available) for support.

Some patients may find it useful to keep a sleep diary to aid sleep management.

For further support and advice parents and carers can access the following websites

https://thesleepcharity.org.uk/ Advice and support for all age groups, including a helpline.

https://contact.org.uk/ For families with disabled children.

https://cerebra.org.uk/ For families of children with brain conditions.

If the patient or carer is unable to utilise sleep hygiene advice, then go to **step 3**.

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Step 2. Follow up

At the follow up appointment in primary care

- Discuss with the patient and/or carer whether or not **sleep hygiene** measures have been effective, suggest methods to optimise these measures if possible
- Discuss what support has been accessed, online or from other health care professionals
- Assess whether interventions for medical, medication or social causes of sleep difficulties have been effective

If sleep hygiene measures and support have been utilised and are showing a positive impact, then advise the patient/carer to continue - **no follow up needed**.

If, after optimising sleep hygiene measures and support mechanisms, they are unsuccessful go to **step 3**.

Step 3. Referral

Sleep hygiene measures and support are the main strategies for reducing sleep difficulties in children, in most cases this can be managed in primary care.

In persistent and more challenging cases further support may be required, dependent on the child's age and co-morbidities. Referral to specialist services should only be considered after:

- Full optimisation of sleep hygiene measures in primary care (see **step 1**)
- Support has been accessed online and from local services (such as school nurse, health visitor, childrens centre) (see **step 1**)
- Medical, medication and social causes of sleeping difficulties have been addressed as far as is reasonably practical within a primary care setting

Referral options include:

- Referral to a local sleep service for young people if available (Currently available for patients aged 2-19 years with a West Lancs GP)
- Patients can self-refer to the NHS Talking Therapies service (in Blackpool, Healthier Minds) if aged 16+ (18+ in South Cumbria) and sleep difficulties are related to low level anxiety or depression
- Referral to CAMHS **only** for a specific co-morbid mental health problem meeting their acceptance criteria, or via the Initial Response Service where available – **do not** refer for sleep support alone
- Children who attend a specialist school may be reviewed by their visiting paediatrician, if available
- Children who have utilised sleep hygiene measures and still present with persistent sleep difficulties, who **are already under the care and follow up of a relevant specialist** should be referred to their specialist (e.g. paediatrician, neurologist, learning disability service)

Referrals must include a full account of which measures have been trialed, including their effectiveness and time scales.

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Step 4. Specialist Assessment

- Medical history and review of medical causes of sleep disorder
- Mental health and psychiatric history and assessment
- Medication review including consideration of medications contributing to sleep disorder
- Sleep history, potentially in the form of a sleep diary
- Revision of sleep hygiene measures
- Treatment aims and target symptoms must be documented

If the specialist considers the patient to have a sleep disorder which cannot be resolved by non-pharmacological measures and that is having a detrimental impact to the patients wellbeing, then a trial of melatonin may be considered (in some cases off-label) in the following patient groups **(RAG rating Amber 0)**:

- **Children with learning disabilities**
  Consider behavioural interventions for sleep problems in children and young people 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 (or a specialist paediatrician) 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).
- **Children 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).
- **Children and adolescents with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome**
  If a pharmacological intervention is needed to aid sleep, consider melatonin and only use it following consultation with a specialist paediatrician or psychiatrist with expertise in the management of autism or paediatric sleep medicine. (CG170)
  In practice, this may include other prescribers within the specialist team (e.g. specialist nurses).
- **Cerebral palsy**
  Manage treatable causes of sleep disturbances that are identified in children and young people with cerebral palsy. If no treatable cause is found, consider a trial of melatonin, particularly for problems with falling asleep. (NG62)
- **Children with complex neurodevelopmental disorders that the specialist considers eligible**

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

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Step 5. Prescription

Preparations and dosing advice

The available relevant product and condition specific, licensed and/or BNFc dosing information is included below to aid treatment and prescribing decisions.

First line (unlicensed indication) - Melatonin 2mg MR tablets [BNFc]
Initially 2 mg once daily, increased if necessary to 4–6 mg once daily, dose to be taken 30–60 minutes before bedtime; maximum 10 mg per day.

First line for the treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) and/or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient (licensed indication) - Melatonin 1mg and 5mg MR tablets (Slenyto)
Child 2–17 years Initially 2 mg once daily, increased if necessary to 5 mg once daily, dose to be taken 30-60 minutes before bedtime; maximum 10 mg per day.

First line in insomnia in patients with ADHD, where sleep hygiene measures have been insufficient, initiated under specialist supervision (licensed indication) – Child 6–17 years
Adaflex IR tablets - Initially 1–2 mg once daily, dose to be taken 30–60 minutes before bedtime, increased if necessary up to 5 mg once daily. Dose can be increased in steps of 1 mg at weekly intervals.
Ceyesto 3mg tablets - 3 mg dose is taken 30-60 minutes before bedtime. Maximum dose 3mg.

Frequency Once daily

Route

MR tablets – Oral, with or after food.

IR 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 children 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).

Slenyto MR tablets

May be mixed whole into food or drink (e.g. yoghurt, orange juice, or ice-cream) immediately before administration (licensed).

Adaflex tablets

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

Melatonin 1mg/mL oral solution (Ceyesto)

- Licensed for insomnia in children and adolescents aged 6-17 years with attention deficit hyperactivity disorder (ADHD), where sleep hygiene measures have been insufficient.
- Licensed for administration via silicone gastric, duodenal or nasal feeding tubes.
- Use of melatonin liquid (Ceyesto) in children under the age of 6 (unlicensed) is supported by Alder Hey. LSCMMG support prescribing of melatonin liquid (Ceyesto) for patients requiring oral solution, age 2 years and above, weighing at least 12kg (refer to the NPPG for further information on excipient content). Contact the Trust pharmacy if benzoate content is at the upper limit or of concern.
- Care should be taken as to the propylene glycol content of liquid preparations.

  [NB. 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 patient's and carers

Information for patient's and carers is available as a leaflet:
https://www.medicinesforchildren.org.uk/medicines/melatonin-for-sleep-disorders/

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

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

Step 6. Review and 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.

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If the specialist team, together with the patient and/or family/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 school 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.

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 school 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.

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Melatonin treatment should not be considered as indefinite. The long term safety of melatonin therapy in children has not been established. 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, a revisiting of sleep hygiene measures along with consideration of new services available to support the young adult would be 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, '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, 'Autism spectrum disorder in under 19s: support and management', 2013

National Institute for Health and Care Excellence, 'Autism spectrum disorder in under 19s: support and management (CG170)', 2013 (updated 2021)

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

BNFc, 'Melatonin', 2023

Medicines for Children, 'Medicines for sleep disorders', https://www.medicinesforchildren.org.uk/medicines/melatonin-for-sleep-disorders/

Version Control

Version Number	Date	Amendments Made	Author
Version 1	September 2023	New document	JG
Version 2	February 2024	Ceyesto liq added	JG
Version 3	November 2024	Sentence added to liquid	JG
Version 4	April 2025	Link to adult guidance added	JG

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