Corby Clinical Commissioning Group
Kettering General Hospital NHS Trust
Nene Clinical Commissioning Group
Northampton General Hospital NHS Trust
Northamptonshire Healthcare Foundation Trust

# Sleep disorder guidelines

This pathway applies to children and adolescents age 2-19 with sleep disorder associated with

- ADHD
- ASD
- Any additional needs including behavioural and physical disability
- Sleep deprivation causing symptoms under care of paediatricians

It applies to those who are treatment naïve and those already taking melatonin.

It does not include children with neurotypical symptoms;

- Night terrors and other sleep problems in the preschool group should be dealt with by HVs (with guidance from Sleep Solutions)
- Sleep apnoea
- Nocturnal epilepsy

## Melatonin

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. It is commonly used for the treatment of sleep disorders in children with Attention Deficit Hyperactivity Disorder (ADHD) but the evidence for this is poor.

Only 1 form of melatonin (Circadin) is currently licensed in the UK for the short-term treatment of primary insomnia, in adults who are aged 55 years or over. All other melatonin products are unlicensed “specials”. Thus there is no licensed product available for use in children.

In its evidence summary of melatonin (NB not formal NICE guidance), NICE noted that “Limited evidence for unlicensed melatonin products was identified from 2 small (n=105 and 19) short-term RCTs and 1 small, long-term follow-up study (n=94). The evidence suggests that unlicensed melatonin products, taken for 10 days to 4 weeks, may reduce sleep onset latency (the time taken for a child to go to sleep) in children with sleep onset insomnia and ADHD by approximately 20 minutes. In addition melatonin may improve average sleep duration by 15 to 20 minutes. However, there are limitations to these small studies, and longer term efficacy is unclear”
https://publications.nice.org.uk/esuom2-sleep-disorders-in-children-and-young-people-with-attention-deficit-hyperactivity-disorder-esuom2/

Unlicensed “specials” such as melatonin can be very expensive, depending on where they are sourced from. GP prescribing costs for melatonin were approximately £300K in 2012-13, with additional prescribing costs incurred by prescribers in Northamptonshire Healthcare Foundation Trust and Northampton General Hospital.

Given the poor evidence-base and the high costs, the Northamptonshire Commissioning Delivery Executive (NCDE) has agreed that melatonin is unlikely to be a cost-effective intervention and it should no longer be routinely used as a first-line intervention for children with sleep disorders. Extra capacity has been resourced for behavioural interventions via Sleep Solutions and this should be the first-line treatment.

**The aim of these guidelines is to improve the services offered to these children and to reduce reliance on melatonin.**

## Treatment naïve children

The first-line treatment is referral of the child/family to Sleep Solutions

NB attendance at the sleep clinic for some children may be problematic.
This may include children who are

1) Blind or a significant visual impairment,
2) Children with mid line brain defects
3) Neurodegenerative disorders
4) Survivors of severe encephalopathy, encephalitis or meningitis
5) Survivors of hypoxic ischaemic encephalopathy / birth asphyxia
6) Brain stem disorders or conditions associated with them i.e. Rett syndrome
7) Post severe head injury

In these clinical situations there may be physiological problems in melatonin productions and regulation however prior approval is still required, with evidence of proposed benefit.

The consultant should explain the limited, if any, benefit of melatonin and side effect profile of alimemazine. (Any prescriptions for alimemazine should be for a maximum of 5 days). Emphasise the proven benefit of behavioural approach.

Referral to the sleep clinic must be via the consultant but self-referral will be undertaken by the child's parent(s). The consultant will provide the parents with the referral form and will notify Sleep Solutions that the self-referral has been recommended.

http://nww.pathfinder-rf.northants.nhs.uk/nene/conditions/mental-health/child-and-family/

***Melatonin should not be considered unless confirmation can be obtained from Sleep Solutions that the family have completed the recommended treatment programme and this has been unsuccessful.***

***Melatonin is double red for all new initiations and prior approval must be sought by the consultant.***

Melatonin will only be initiated where a child has failed to gain improvement after attendance at the sleep clinic and having followed the recommended program. It is anticipated that consequently the use of melatonin will fall significantly and therefore any prescribing initiated after 1st November 2013 will be via prior approval only i.e. melatonin is categorised as "double red" for new initiations.

- ✓ Prescribing may be passed to the GP for shared care after 2 months provided the conditions in the Shared Care Guidelines have been met and Prior Approval has been requested by the consultant and has been agreed
- ✓ Melatonin capsules should be prescribed as Ramatonin where possible
- ✓ The Shared Care Guidance is available on Pathfinder at http://nww.pathfinder-rf.northants.nhs.uk/nene/therapeutics/traffic-light-drugs/melatonin/
- ✓ Parents will be given a leaflet explaining the treatment, so that their expectations are clear

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## Children already taking melatonin

Existing patients will remain under the shared care arrangements between the consultant and the GPs until such time as it is appropriate for them to stop treatment.
These children will be invited to / referred for a paediatrician clinic review if they have not been reviewed in the last 6 months.

NB There is no requirement to obtain retrospective prior approval for existing patients currently under shared care arrangements.

At clinic review, children will be stratified into 3 groups as below -
(If DNA discharge according to standard policy, but repeat scripts should not be issued without review).

Aims for all groups are -

- ✓ Discuss research information on melatonin and other medications
- ✓ Emphasise the benefit of behavioural approach
- ✓ Referral to Sleep Solutions whilst melatonin is reduced
- ✓ Joint sleep plan
- ✓ Reduce melatonin dosage
- ✓ Stop melatonin treatment

Refer to sleep solutions (as above) with clear message about added benefit of behavioural approach

Divide children into melatonin responders, partial responders or non-responders

1. **Melatonin Responders**
   - ✓ Offer parents option of weaning or trial off treatment
     i.e. reduce dose or intermittent 4 weeks on/off
   - ✓ If trial off treatment is unsuccessful – keep sleep diary and refer to Sleep Solutions via joint working process

2. **Melatonin Partial responders**
   - ✓ Maintain melatonin
   - ✓ Refer to sleep solutions
   - ✓ Sleep Solutions will advise paeds when ready for weaning off melatonin

3. **Melatonin Non-responders**
   - ✓ Stop melatonin
   - ✓ Refer to Sleep Solutions

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