SY ICB and Bassetlaw Shared Care Protocol for Melatonin

For the treatment of sleep disorders in children and young people up to 18 years (off-label use)

Shared care protocol developed by:

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Review by: December 2028

Age Scope and Discontinuation of Shared Care

Shared care arrangements involving paediatric services will end when the patient reaches 18 years of age. At this point, primary care prescribers may also decide to discontinue prescribing, as the existing shared care agreement will no longer be applicable.

Patients and their families will be informed of this cessation by the specialist at the time treatment is initiated.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet
- Discuss with the parent/carer the time-limited nature of the shared care agreement and ensure they understand that prescribing responsibility may not continue in primary care once the child is discharged from Paediatrics (18 years of age).
- To discuss the importance of sleep hygiene and regular sleep routine with patient.
- Before initiating melatonin, a full trial of sleep hygiene measures and behavioural management should have been attempted and found to be ineffective in achieving satisfactory results.
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate treatment as outlined in section 5 and prescribe for at least 1 month or until response has been confirmed and optimal dose achieved, before primary care prescribing is requested.
- Once treatment is optimised, complete the shared care request form see Appendix 1. Shared care Request's and send to patient's GP practice detailing the diagnosis/indication, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13).
- Prescribing should only be transferred after receiving confirmation from the GP that they are willing to take over melatonin prescribing, see Appendix 2
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- After 3 months of treatment, evaluate the treatment effects and consider stopping treatment if no clinically relevant treatment effect is seen. Conduct the scheduled reviews and monitoring in section 8 and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- Wherever possible and where applicable, evaluate the ongoing need for Slenyto® (or other non-formulary options, e.g., melatonin capsules or liquids other than Ceyesto®) and consider whether a switch to a more cost-effective option is feasible, see formulary choices flowchart.
- Provide advice on the need for contraception to male and female patients on initiation and at each review, see 12.
- Reassume prescribing responsibilities if a female patient becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

- The patient should normally remain under specialist care. However, where ongoing specialist coordination is not required, the specialist must ensure timely access to advice and intervention, without the need for a new referral.
- Review the young person's treatment as they approach discharge from the Paediatric pathway (just prior to their 18th birthday) to assess ongoing clinical need:
  - Consider and, if appropriate, facilitate the discontinuation of medication at this stage.
  - Where treatment is discontinued, provide guidance on lifestyle and sleep management strategies, if relevant, to support ongoing wellbeing.

Primary care responsibilities

- To refer appropriate patients to secondary care for assessment
- Provide a written response to the specialist's shared care request within 14 days of receipt. See Appendix 2
- Adjust the dose of melatonin prescribed or stop treatment if advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any issues/concerns to the specialist. Do
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop melatonin and make an urgent referral to the specialist if the patient experiences an allergic reaction or anaphylaxis and report any serious adverse reaction to the appropriate bodies e.g. MHRA
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- In the event that the GP is not able to prescribe, or where the shared care is agreed but the consultant is still prescribing certain items e.g. Hospital only product; the GP will provide the consultant with full details of existing therapy promptly on request.
- Primary care clinicians will not be required to prescribe hospital-only medicines, or formulations that are unlicensed or not approved for use in the UK.
- For medication supplied from another provider GPs are advised to follow local recommendations for Guideline Recording Specialist Issued Drugs on Clinical Practice Systems-Sheffield
  Rotherham Rotherham Factsheet Recording Non practice drugs
  Doncaster Doncaster Guideline Recording medicines prescribed elsewhere into GP practice clinical system.pdf
  Barnsley - Adding Hospital Prescribed Drugs to S1
  Barnsley Guideline Adding Hospital Prescribed Drugs to EMIS WEB.pdf

Patient and/or carer responsibilities

- To be fully involved in, and in agreement with, the decision to move to shared care
- To make ongoing efforts in maintaining sleep routine and sleep hygiene measures
- To read the product information given to them
- Take melatonin as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Inform the specialist and/or GP practice if they decide to stop or have already stopped taking melatonin.
- Attend regularly for monitoring and review appointments with primary care and specialist and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of melatonin with their pharmacist before purchasing any OTC medicines.
- Avoid alcohol while taking melatonin as it may make some side effects worse. Avoid recreational drugs.

- Not to drive or operate heavy machinery if melatonin affects their ability to do so safely.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Background

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Melatonin, a hormone produced by the pineal gland, regulates the circadian rhythm and sleep–wake cycle. Its secretion is influenced by light exposure via the retina. In people with neurodevelopmental conditions or visual impairment, melatonin production or regulation may be disrupted, contributing to sleep disturbances.

Evidence from randomised controlled trials and clinical experience suggests melatonin can be effective in treating sleep-onset insomnia and delayed sleep phase syndrome in children with conditions such as autism spectrum disorder (ASD), ADHD, epilepsy, cerebral palsy, learning disabilities, and visual impairment.

According to NICE NG11 guidance Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges use of melatonin may also be considered in children, young people, and adults with a learning disability where coexisting mental or physical health conditions contribute to the development or persistence of behaviours that challenge. Its use is generally reserved for children and young people with developmental or psychiatric conditions who experience significant sleep disturbances—such as delayed sleep onset or recurrent night-time awakenings—particularly where behavioural interventions and sleep hygiene have proven insufficient or are difficult to implement.
Non-pharmacological approaches remain first-line. Behavioural strategies and good sleep hygiene are often highly effective and should be assessed and reinforced at every review, regardless of whether melatonin is prescribed.

Insomnia in early childhood can present in various ways, ranging from difficulty falling asleep to frequent night-time awakenings or early morning waking. These sleep disturbances are commonly grouped into four behavioural phenotypes:

- **Sleep-onset difficulties**
- **Sleep maintenance or fragmented sleep**
- **Early morning awakenings**
- **Complex or mixed sleep issues across multiple domains**

Recognising these phenotypes enables a more focused clinical assessment and helps tailor management strategies to the individual child. It's also important to evaluate any coexisting factors—such as neurodevelopmental disorders, medical conditions, or environmental influences—that may contribute to or exacerbate sleep problems.

2. Indications

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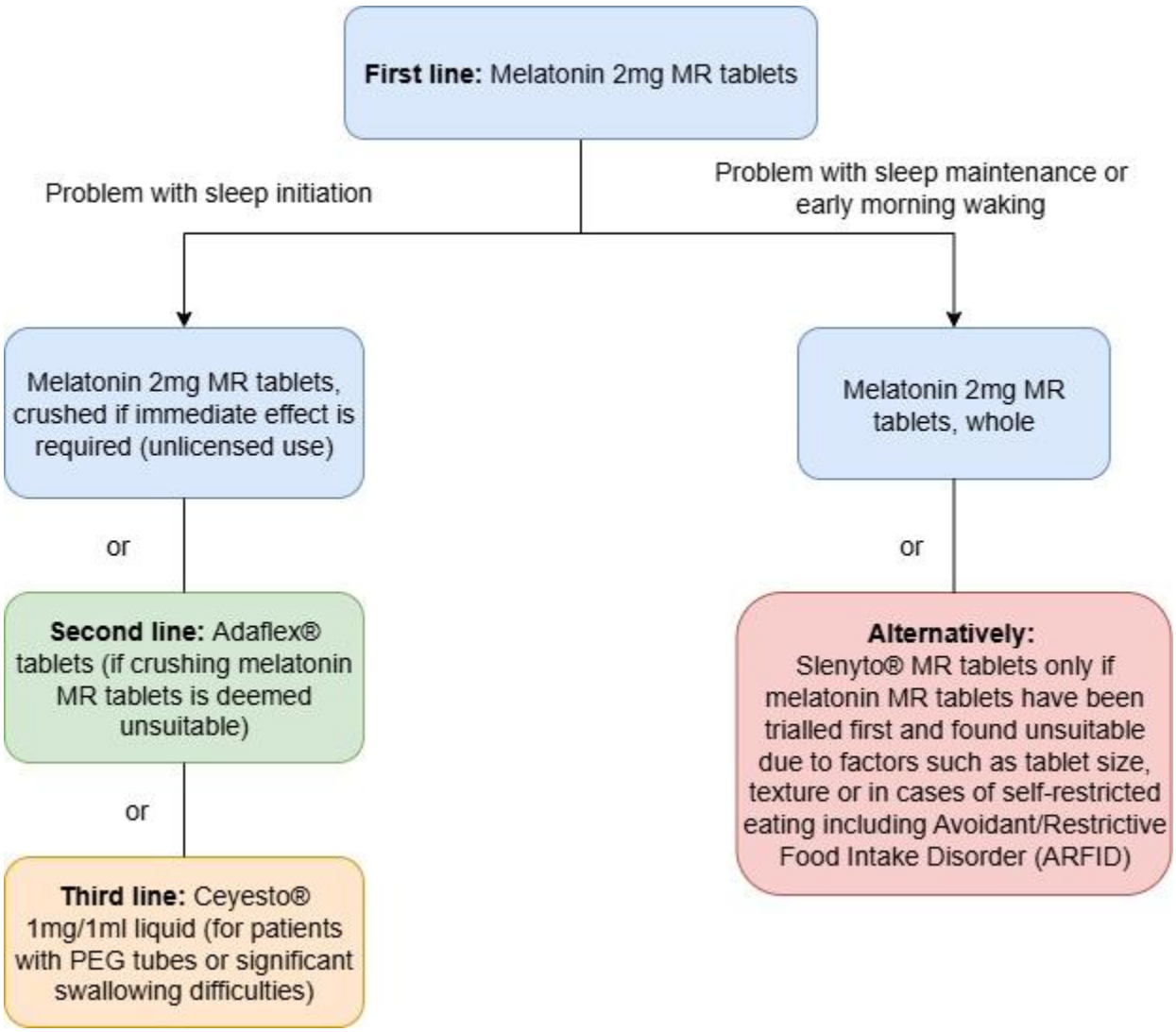
Melatonin is indicated for the treatment of sleep disorders (e.g. sleep onset delay or recurrent nighttime wakening) in children and young people with developmental and psychiatric disorders, see Melatonin | Drugs | BNFC | NICE and insomnia in adults with learning disabilities and behaviour that challenges, see Melatonin | Drugs | BNF | NICE.

For formulary choices please see flowchart below:

Formulary choices flowchart (the options listed below reflect current cost-effective choices consistent with established clinical practice).



2.1. Problems with sleep initiation (falling asleep) where immediate release formulations are required:

- **Melatonin 2 mg modified-release (MR) tablets (first line and prescribed as generic)** may be **crushed*** to achieve an **immediate-release effect**. Although this use is **unlicensed**, it is widely accepted in clinical practice, particularly for patients with swallowing difficulties.
  *For administration details what is off please see Administration details

- **Adaflex®** (immediate-release melatonin) is an alternative option when crushing melatonin MR tablets is deemed unsuitable:
  - For doses **up to 4 mg**, crushed **Melatonin 2 mg MR tablets** may be used where and if possible (more cost effective option).
  - For doses **of 5 mg or more**, **Adaflex® tablets** are preferable. These are **licensed to be crushed**, making them also suitable for patients with swallowing difficulties.

- **Ceyesto® 1 mg/ml oral solution** for patients with **PEG tubes or significant swallowing difficulties**.

2.2. Problems with sleep maintenance or early morning waking, where prolonged release formulations are required**:**

- **Melatonin 2mg prolonged- release tablets (first line and prescribed as generic)** should be prescribed, to be swallowed whole 30-60 minutes prior to bedtime (off –label indication). A second dose should not be given during the night.

- **Slenyto® MR tablets** should be considered only for patients who have trialled melatonin 2 mg modified release (MR) tablets and found them unsuitable due to factors such as tablet size, texture, or in cases of self-restricted eating including Avoidant/Restrictive Food Intake Disorder (ARFID), where the smaller tablet size of Slenyto® offers a clinical advantage.
  - Where appropriate, off-label use of melatonin 2 mg MR tablets should be explored before initiating Slenyto®, in order to support cost-effective prescribing and clinical practice. If Slenyto® is prescribed, the rationale should be clearly documented in the patient's clinical notes, and the GP informed.
  - For children aged approximately 5–6 years and older who remain on Slenyto®, efforts should be made to transition suitable patients to generic MR melatonin or Adaflex® tablets, depending on the child's individual insomnia phenotype and ability to manage standard preparations.

2.3. Problems with both sleep initiation and sleep maintenance/fragmental sleep/early morning awakening

- In children and adolescents who have problems with both sleep initiation and sleep maintenance/early morning awakening, a combination of immediate release and whole prolonged-release tablets may be required.

All patients on preparations not listed should be reviewed and if there is a continued need for melatonin, switched to a preparation listed within the shared care protocol.

Please note that in certain cases, a specialist may request that melatonin be prescribed by specific brand (Circadin ®, Slenyto®). If this is required, it will be clearly communicated to the GP along with the clinical justification.

3. Locally agreed off-label use

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The use of melatonin preparations for conditions outside of their licensed indications constitutes **off-label use**. Any off-label prescribing will be discussed between specialist and the patient or caregiver as per specialist responsibilities. The initiating specialist retains overall clinical responsibility for ensuring the appropriateness of off-label use.

This requires:

- **Informed consent** from the patient, parent, or guardian, and
- **Clear documentation** in the patient's clinical notes.

Melatonin 2 mg prolonged-release (MR) tablets are used off-label in children. When an immediate-release effect is required, the tablets can be crushed, although this is not within the licensed use.
These tablets are licensed as monotherapy for the short-term treatment of primary insomnia characterised by poor sleep quality in adults aged 55 years and over.

Adaflex® tablets are used off-label for indications other than ADHD when an immediate-release melatonin formulation is required and are also prescribed off-label for children under 6 years of age.

Adaflex® is licensed for the treatment of insomnia in children and adolescents aged 6 to 17 years with ADHD, where sleep hygiene measures have been insufficient.

Slenyto® prolonged-release tablets are used off-label for children with ADHD under the age of 6 years and for those over 17 years of age.
Slenyto® is licensed for the treatment of insomnia in the following groups, where sleep hygiene measures have proven insufficient:

- treatment of insomnia in children and adolescents aged 2-18 years with Autism Spectrum Disorder (ASD), and / or neurogenetic disorders with aberrant diurnal melatonin secretion and /or nocturnal awakenings
- treatment of insomnia in children and adolescents aged 6-17 years with attention-deficit hyperactivity disorder (ADHD)

Ceyesto® 1 mg/1 ml oral solution is used off-label in children under 6 years of age and those without ADHD. It is licensed for the treatment of insomnia in children and adolescents aged 6 to 17 years with Attention Deficit Hyperactivity Disorder (ADHD), where sleep hygiene measures have proven insufficient.

4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see BNF, BNFC & SPC for comprehensive information.

Contraindications:

- Hypersensitivity to the active substance or to any of the excipients.

Cautions:

- The manufacturer of the UK licensed product advises melatonin should not be used in patients with autoimmune diseases, liver disease and some rare hereditary galactose intolerance, total lactase deficiency or glucose-galactose malabsorption (due to it containing lactose). Full details of cautions are given in the Summary of Product Characteristics SmPC.

- Please note that **Ceyesto® 1mg/1ml oral solution contains propylene glycol and benzyl alcohol as excipients**, see SmPC. While the quantities present are considered acceptable (see calculations and examples below), **caution should be exercised if the patient is prescribed other liquid formulations containing the same excipients, as accumulation could result in exceeding the recommended limits**.

Ceyesto liquid contains

• Propylene glycol: 52 mg per 1 ml dose

• Benzyl alcohol: 6 mg per 1 ml dose

• Each 1 ml of oral solution contains 1 mg of sodium.

Safety of excipients with Ceyesto®:

The EMA (European Medicines Agency) and NHS guidance (e.g. NPPG Liquid-Choice) set thresholds for propylene glycol intake in children. For young children (1 month to 4 years), the threshold is 50 mg/kg/day

Questions and answers on propylene glycol used as an excipient in medicinal products for human use

Example for children 3-6 years old
• For a typical 3-year-old child (mean weight ~14 kg see BNFC), the maximum acceptable daily intake of propylene

glycol is around 700 mg/day.
• If such a child is given the *maximum* dose of 10 mg melatonin/day (via Ceyesto), that equates to 520 mg of propylene glycol (since 1 mL gives 52 mg PG). This is *below* the threshold.

Benzyl alcohol

The EMA recommend for products that contain benzyl alcohol 'do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist' as there is an 'increased risk due to accumulation in young children (less than 3 years old).' 'Young children (less than 3 years old) may not be sufficiently mature to metabolise and eliminate benzyl alcohol as efficiently as adults.' This risk of accumulation is in newborn babies (pre- and full-term) and is due to metabolic immaturity.

It is therefore suggested that Ceyesto® oral solution is suitable for patients aged 3 years and over. Regarding use in children aged 3 years and over, the NPPG advises a maximum acceptable daily intake of 5mg/kg of benzyl alcohol in children over 4 weeks of age.

Therefore, for a 3-year-old (mean weight 14kg as per BNFC), the maximum acceptable daily intake of benzyl alcohol is 70mg. As each 1ml of Ceyesto® oral solution has 6mg benzyl alcohol, a maximum dose of 10mg melatonin per day will result in 60mg benzyl alcohol, which is less than the maximum acceptable daily limit for a 3-year-old child. This is for illustrative purposes only.

5. Initiation and ongoing dose regime

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- Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimised and with satisfactory investigation results.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the specialist.

Initial stabilisation:

The loading period must be prescribed by the specialist.

- The recommended starting dose is 2mg daily before bed- time.
- If the response is inadequate, increase the dose to 4 mg or 5 mg daily at bedtime, depending on the preparation used.

The specialist team will titrate any increase in dose needed and any change required will clearly be communicated to the primary care clinician.

Maintenance dose (following initial stabilisation):

The initial maintenance dose must be prescribed by the initiating specialist.

- Doses above 4mg/5mg daily are rarely needed. The maximum daily dose is 10 mg. The licensed maximum daily dose of Adaflex® is 5mg.
- Melatonin works best in conjunction with Behavioural interventions, and parent education programme.
- Evaluate after at least 3 months and consider stopping if no clinically relevant treatment effect is seen.
- Monitor at regular intervals (at least every 6 months) to check that it is still the most appropriate treatment or if an ongoing treatment is still required.

Conditions requiring dose adjustment:

- If a lower treatment effect is seen after titration to a higher dose, consider a down-titration to a lower dose before deciding on a complete discontinuation of treatment.

Switching preparations:

If a formulation of melatonin has been trialled and have not provided expected effect, a period of 14 days without melatonin can be trialled. Reiterate the importance of sleep hygiene. For best success, agree a suitable time to stop treatment (e.g., during school holidays), avoiding periods of stress (e.g., during exams).

A re-bound worsening in sleep pattern may occur initially but this may improve over time.

If sleep deteriorates significantly after a period of 14 days, then a switch to a different brand of melatonin tablet can trialled, see Formulary choices . Review response after 2-4 weeks. Use the lowest effective dose and do not exceed previously prescribed dose.

6. Pharmaceutical aspects

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Route of administration:	oral
Formulation:	• Melatonin 2mg modified- release tablets. • Adaflex® immediate-release tablets. • Slenyto® modified- release tablets. • Ceyesto®1mg/ml oral solution
Administration details:	• **Melatonin 2mg modified-release tablets** should be taken 1-2 hours before bedtime and after food. • Immediate-release formulations (**Adaflex®**) should be taken on an empty stomach, 2 hours before or 2 hours after food - intake with carbohydrate-rich meals may impair blood glucose control. • The immediate-release tablet **Adaflex®** may be crushed and mixed with water immediately before administration, see EMC. • The modified-release tablet **Slenyto®** may be mixed whole into food or drink (e.g. yoghurt, orange juice, or ice-cream) immediately before administration. • **Ceyesto® 1mg/ml oral solution**- food can increase the plasma melatonin concentration. Intake of melatonin with carbohydrate-rich meals may impair blood glucose control for several hours. It is recommended that food is not consumed 2 hours before and 2 hours after intake of this medicinal product.
Other important information:	• Give the medicine at about the same time each day so that this becomes part of the child's daily routine.

7. Significant medicine interactions

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The following list is not exhaustive. Please see BNF, BNFC or SmPC for comprehensive information and recommended management.

The details below are not a complete list and the BNF, BNFC and the SmPC remain authoritative.

Concomitant use of the following medicinal products is not recommended:

- Fluvoxamine increases melatonin levels (by 17-fold higher AUC and a 12-fold higher serum Cmax) - the combination should be avoided.
- Alcohol should not be taken with melatonin, because it reduces the effectiveness of melatonin on sleep.
- Benzodiazepines/non-benzodiazepine hypnotics sedative properties are enhanced by melatonin.
- Thioridazine and imipramine

- There is a theoretical risk that any CYP1A2 inhibitors could cause an increase in melatonin levels (e.g., oestrogens, quinolones), if a patient on melatonin is started on any medication that inhibits CYP1A2 then advise and monitor about the possibility increased drowsiness and consider if a reduction of the dose of melatonin is needed.
- CYP1A2 inducers such as carbamazepine and rifampicin may give rise to reduced plasma concentrations of melatonin.

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in the immediate future will prescribing and monitoring be transferred to primary care. Back to top

Baseline investigations:

- Assessment is based on clinical history and patient feedback.
- Use a sleep diary to support assessment.

Initial monitoring:

- Review after 2 weeks, then monthly until the optimal dose is established.
- After 3 months of treatment, evaluate the treatment effects and consider stopping treatment if no clinically relevant treatment effect is seen.
- The general aim is to use melatonin as a short-term treatment; this will be made clear to the parents and carers at initiation.

Ongoing monitoring:

- In children, monitor growth annually by recording height and weight.
- To review the patient in clinic, regularly until optimum dose is established and then 6 -12 monthly reviews
- An attempt to withdraw/have a break in treatment should be made at least every 6 months. A trial of withdrawal may be tried earlier than 6 months if the clinician and parents decide it is appropriate. Also, a longer treatment period may be appropriate in some patients as advised by the specialist clinician.
- Sleep hygiene should be reinforced throughout treatment and prior to any attempt to stop.
- When a patient is reviewed, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.

9. Ongoing monitoring requirements to be undertaken by primary care

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency
Adherence to sleep hygiene (see Appendix 3)	Annually
Compliance and continued response to treatment	Annually
Signs of adverse effects	Annually

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics. There is no risk from abrupt withdrawal of melatonin.

In the paediatric population,a low frequency of generally mild side effects have been reported. The most common side effects were headache,hyperactivity,dizziness and abdominal pain.

Stopping treatment will be considered in the below scenarios:

- Sleep latency (time taken to fall asleep after getting into bed) - less than 60 minutes.
- Total sleep time – more than 8 hours if <10 years/ more than 6 hours if >10 years
- Evidence of non-engagement with sleep hygiene measures.
- Treatment may be stopped by the GP or the specialist if any of the above presents.
- For best success, mutually agree with the patient a suitable time to stop treatment, for example during school holidays, avoiding periods of stress e.g., during exams.
- A 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 for another 6 months alongside sleep hygiene measures. Start at 2mg daily, increasing as per above, (doses above 4mg / 5mg rarely needed. Total daily dose should not exceed 10mg daily or the maximum of previous dose agreed by specialist).
- As outlined in the specialist responsibilities above, when a patient approaches 18 years of age, a specialist review to support the discontinuation of melatonin will be required before primary care stops treatment. This ensures that the cessation is managed safely and appropriately.

11. Advice to patients and carers

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The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient should be advised to report any of the following signs or symptoms to their prescriber without delay:

- Allergic reactions. These are uncommon and may include rash.
- Anaphylaxis. This may occur on rare occasions. The patient should be advised to call 999 in the first instance.

The patient should be advised:

- That melatonin is intended as a short-term intervention and must be used in line with sleep hygiene techniques.
- If melatonin being prescribed is a product / preparation being used off label. Its long-term effects are unknown.
- Regular breaks in treatment should be encouraged to assess if continued need. Stopping treatment should be discussed and documented after 2 years.
- Patient will be informed by the initiating specialist that there are no arrangements of continuation of shared care beyond the age of 18.

Patient information:

Melatonin for sleep disorders – Medicines For Children

Good-sleep-habits-for-children-with-Learning-Difficulties.pdf

Home - The Sleep Council

Home - Teen Sleep Hub

Children - The Sleep Charity

Advice Sheets - The Sleep Charity

Diet & Sleep - The Sleep Charity

The Childrens Sleep Charity Leaflets

Bedroom Environment - The Sleep Charity

Bedtime Routines - The Sleep Charity

Fall asleep faster and sleep better - Every Mind Matters - NHS

12. Pregnancy, paternal exposure and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

There is no data from the use of melatonin in pregnant women. Exogenous melatonin readily crosses the human placenta. Considering the lack of clinical data melatonin is not recommended during pregnancy or in females of child-bearing potential and not using contraceptives.

Information for healthcare professionals:

Search Results Melatonin - (emc)

Adaflex 1 mg tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Ceyesto 1mg/ml Oral Solution - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

Breastfeeding:

Information for healthcare professionals: There is insufficient data on the excretion of melatonin / metabolites in human milk. Endogenous melatonin is secreted in human milk. Considering the lack of clinical data melatonin should not be used during breast-feeding.

Paternal exposure:

High doses of melatonin and use for longer periods than indicated may compromise fertility in humans. Melatonin is not recommended in women and men planning pregnancy.

13. Specialist contact information

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Support from the specialist team should be available within 14 calendar days.

Sheffield

Name: Dr Hemant Kulkarni

Role and specialty: Consultant in Paediatric Respiratory Medicine, Sheffield Children`s Hospital

Daytime telephone number: 0114 2717400

Email address: contact respiratory secretaries scn.tr-respiratory.secretaries@nhs.net

Alternative contact: respiratory secretarial team 0114 3053848

Out of hours contact details: contact a member of the on call respiratory team via switchboard 0114 2717000

Doncaster:

Office Hours – Specialist DBH FT Paediatric Dept Tel: 01302 366666

Out of hours – On-call Paediatrician DBHFT Tel: 01302 366666

RDASH FT CAMHS Dept Tel: 01302 796191 ADHD Clinic – Address: Jubilee 2, Tickhill Road Site. (01302) 796880, 789149

Barnsley:

CAMHS

Name	Office Number	Email
Dr Ovidiu Sandica, Consultant Psychiatrist	01226 644829	Ovidiu.sandica@swyt.nhs.uk
Dr Lourence Lewis-Hanna, Consultant Psychiatrist	01226 644829	Lourence.lewis-hanna@swyt.nhs.uk
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Dr Hilary Reed, Speciality Doctor	01226 644829	Hilary.reed@swyt.nhs.uk
Dr Aly Middleton, Speciality Doctor	01226 644829	Aly.middleton@swyt.nhs.uk
Erin Parkinson, Nurse Prescriber (ADHD)	01226 644829	Erin.parkinson@swyt.nhs.uk

Rotherham:

CDC 01709 428850 or rgh-tr.cdc@nhs.net

Community paediatrics and Special school clinics: 01709 42 6379 or rgh-tr.rotherhampaediatrics@nhs.net

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

Support, Education and Information

Sheffield

Child Development and Neuro Disability Team - Sheffield **Telephone No:** 0114 2717609	**Sleep Service** Sheffield Children's NHS Foundation Trust **Telephone No:** 0114 2717400	**CAMHS - Sheffield Teams** Centenary: 0114 2262348 Beighton: 0114 2716540	**Pharmacy department** Sheffield Children's NHS Foundation Trust **Telephone No:**0114 2717259

Sheffield Children's NHS Foundation Trust - Melatonin Patient Information Leaflet (Available from SCHFT pharmacy department)

Doncaster:

Office Hours – Specialist DBH FT Paediatric Dept Tel: 01302 366666

Out of hours – On-call Paediatrician DBHFT Tel: 01302 366666

RDASH FT CAMHS Dept Tel: 01302 796191

ADHD Clinic – Address: Jubilee 2, Tickhill Road Site. (01302) 796880, 789149

Barnsley:

CAMHS 01226 644829

or Community Paediatrics 01226 644872

Rotherham:

TRFT: Support, education and information
Community paediatricians via Community Bookings on 01709 426379 or rgh-tr.rotherhampaediatrics@nhs.net
CDC paediatricians via CDC admin on 01709 428850 or rgh-tr.cdc@nhs.net
General Paediatricians via paediatric secretaries 01709 424521

Dr McCowen's secretary 01709 424672
Email: rgh-tr.rotherhampaediatrics@nhs.net

Out of hours and at weekends please contact the Paediatric Registrar on call on
01709 820000
Pharmacy Department:
Medicines Information Pharmacist 01709 304126
Paediatric Pharmacist 01709 820000
Ext 8151

RDaSH: CAMHS (Community Services – Rotherham)
Kimberworth Place, Kimberworth Road, Rotherham, S61 1HE
Tel: 03000 215 984
Email: RDASH.Rotherhamcamhsadmin@nhs.net

15. References

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16. Other relevant national guidance

- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/
- NHSE policy – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/
- Electronic Medicines Compendium, Melatonin, Search Results - (emc)
- British National Formulary for Children, available at https://bnfc.nice.org.uk/drugs/melatonin/
- Medicines Health Regulatory Authority. Summary Report for Importation of Unlicensed Medicines. April-June 2018, available from Summary Report for Importation of Unlicensed Medicines April- June 2018

17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

If the patient's condition changes—such as symptom recurrence or the development of adverse effects—the secondary care team should provide timely access to appropriate advice and support without requiring a new referral, even when for some reason patients are no longer under regular follow-up or are not attending secondary care appointments.

Appendix 1. Shared Care Request Template (Specialist to Primary Care Prescriber)

Dear: *[insert Primary Care Prescriber's name]*

Patient name:*[insert patient's name]*
Date of birth: *[insert date of birth]*
NHS Number*: [insert NHS Number]*
Diagnosis/Indication: *[insert diagnosis]*

As per the agreed *SY wide* shared care protocol for *Melatonin*, this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care.

Treatment was started on *[insert date started]* and the brand prescribed is [*insert brand name*]. The current dose is *[insert dose and frequency]*.

If you are in agreement, please undertake monitoring and treatment from *[insert date]*

NB:

Please respond to this request for shared care, in writing, within 14 days of the request being received where possible.

Appendix 2. Shared Care Agreement/Refusal Template (Primary Care Prescriber to Specialist)

Primary Care Prescriber Response

Dear *[insert Doctor's name]*
Patient *[insert Patient's name]*
NHS Number *[insert NHS Number]*
Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment.

Medicine	Route	Dose & frequency

☐ I can confirm **that I am willing to take on** this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

☐ I regret to inform you that in this instance **I am unable to take on** responsibility for the requested prescribing.

Any feedback to secondary care (optional):

Primary Care Prescriber signature: _____ Date: _____

Primary Care Prescriber address

*Appendix 3. Six steps sleep routine**

These six steps should be implemented consistently, 7 days/week:

Step 1. Set a time for the bedtime routine to begin. 'Lights out' is calculated by subtracting the recommended age-appropriate sleep duration (How Much Sleep Do Babies and Kids Need? (sleepfoundation.org) from the desired waking time. The bedtime routine starts 1 hour before 'lights out'.

Step 2. Start the bedtime routine by switching off all screens and having 15 minutes of age-appropriate calm time. This could be quiet toys, crafts, colouring books, card games and fidget toys. This gives an opportunity for quality time with the child before bed.

Step 3. Sleepy supper. Milky and whole-wheat foods are suitable.

Step 4. Bath time, pyjamas, teeth and toilet. If bath time is very stimulating for the child, this can be skipped and done at a different time of day.

Step 5. Settle into bed with the lights low. Story time or a quiet song.

Step 6. Lights out and say 'goodnight'.

In the morning, switch on the lights, give the child a hug and say: 'well done'.

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