Surrey and Borders Partnership NHS Foundation Trust

Surrey Heartlands

Surrey Heartlands Integrated Care System Area Prescribing Committee (APC)

SHARED CARE Guideline – Amber Traffic Light Classification		
Name of medicine	Melatonin 2mg modified release tablets melatonin 1,2,3,4,5mg immediate release tablets, or melatonin 1mg/ml oral solution sugar free	
Indication (including whether for adults and/or children)	For the Treatment of Persistent Sleep Disorders in Children 6-17 years old with Attention Deficit Hyperactivity Disorder (ADHD) NOTE: to be used by practices participating in the Locally Commissioned Service - 12 monthly review monitoring for CNS stimulants, atomoxetine, guanfacine and methylphenidate	
- **APC policy statement reference** (if applicable)	N/A	
Author(s): Alison Marshall **Organisation(s):** Surrey and Borders Partnership NHS Foundation Trust		
Version: 1.1	**APC recommendation date:**	**Review date: Dec 2022**

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.
This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications.
The SCG must be used in conjunction with the APC agreed core roles and responsibilities stated in annex A.
An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Roles and Responsibilities

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Consultant / Specialist

Pre-treatment checks

1. To assess the patient and establish the need for sleep onset treatment in neurodevelopmental disabilities.
2. Consider and discuss treatment options. This should include consideration of contra-indications, interactions and cautions, a discussion of the reasons for treatment, the possible adverse effects and the lack of information in relation to longer-term outcomes including effectiveness and adverse effects
3. To consider melatonin where non-pharmacological strategies have failed, and underlying physical causes are managed where they exist.
4. To consider only where parents, carers or, where appropriate the patient, has completed a sleep questionnaire and sleep diary highlighting problems with sleep latency.

Patient Education

1. Provide verbal and written information to the parents, carers, and where appropriate the patient, and answer their questions about melatonin. This may include information from www.medicinesforchildren.org.uk or www.choiceandmedication.org.uk/sabp
2. Explain to the patient / carer their roles as below, ensuring the patient/carer is aware of the need to review the melatonin every 6 months. Obtain informed consent for the off label prescribing of melatonin if melatonin 2mg MR tablets are prescribed, or if a licensed liquid formulation is prescribed off-label, (melatonin 1mg/mL oral solution sugar free (Colonis Pharma).

Starting Treatment

Note that the modified release formulation of melatonin will assist with *maintenance* of sleep, whereas the immediate release formulation will assist with promoting the *onset* of sleep.

1. Perform baseline checks of physical health (including height, weight)
2. Initiate off label melatonin 2mg modified release tablets.

If an immediate release preparation is required, the licensed melatonin 1,2,3,4, or 5mg tablets should be prescribed. The licence for these tablets permits them to be crushed if patient is unable to swallow a whole tablet.

If necessary, only where the patient has a feeding tube or significant swallowing difficulties, the use of the licensed melatonin 1mg/mL oral solution may be considered. In some cases this may be an off-label use due to variation in licensing of the product from different manufacturers. Consideration should be given when dispensing to the excipients present in the licensed melatonin oral solution, with particular reference to propylene glycol and sorbitol.

3. For information on the suitability of excipients see http://nppg.org.uk/wp-content/uploads/2020/12/Position-Statement-Liquid-Choice-V1-November-2020.pdf

Subsequently

1. Assess and monitor the patient's response to treatment and make dose adjustments where necessary.
2. If treatment is ineffective and discontinued check for possible complications following discontinuation.
3. Undertake any necessary monitoring at face to face clinic appointments (12 monthly when stable): including height, weight, sexual development (this has been seen in animals but not in human use of melatonin) and assess the continuing need for melatonin considering stopping melatonin e.g. 14 day break using an appropriate sleep monitoring tool. Although leukopenia is a known (rare) side effect, regular FBCs are not specifically required.
4. Collate (including on centile charts) and review the physical medication monitoring results received from the patient's GP practice by email every 12 months (received 6 months after the specialist review detailed in point 11) and advise GP of any required actions. The bottom section on the results form received from the patient's GP practice should be completed and the form emailed back to the practice after each GP physical medication review.
5. Assess and monitor the patient's response to treatment and make dose adjustments where necessary.
6. Assess the continuing need for melatonin at 6 monthly review and consider stopping melatonin, e.g. 14 day break every 6 months using an appropriate sleep monitoring tool, and advise GPs on this for patients discharged from specialist care.
7. Maintain good communication with the GP and provide urgent advice on the following telephone number – 0300 2225755. A written letter should be sent to the GP after each clinic visit notifying

the GP of changes in the medication regime, adverse effects and results of the patient's routine monitoring. The GP must be notified of non-attendance at clinic. (NOTE: patients that regularly do not attend their 6 monthly reviews are not appropriate for shared care)

8. Notify the GP of the patient's failure to attend for clinical review or drug monitoring and give advice on stopping the medication (NOTE: patients that regularly do not attend their 6 monthly reviews are not appropriate for shared care)
9. To take responsibility for reviewing the need for ongoing treatment, and stop treatment or agree aftercare when the patient reaches 18 years of age.
10. Any other medicine/indication specific information that will be helpful to the primary care prescriber
11. If treatment is ineffective and discontinued check for possible complications following discontinuation.

Primary Care Prescriber

Maintenance

1. Subsequent prescribing of melatonin as 2mg MR tablets, melatonin 1,2,3,4,or 5mg immediate release tablets, or occasionally the licensed 1mg/1ml oral solution sugar free, as recommended by the specialist and at the dose recommended once the treatment has been established, the patient stabilised and the care of the patient has been transferred and accepted.

In some cases this may be an off-label use of the liquid due to variation in licensing of the product from different manufacturers. Consideration should be given when dispensing to the excipients present in the licensed melatonin oral solution, with particular reference to propylene glycol and sorbitol.

2. For information on the suitability of excipients see http://nppg.org.uk/wp-content/uploads/2020/12/Position-Statement-Liquid-Choice-V1-November-2020.pdf
3. To inform the consultant if unwilling to enter into shared-care arrangements
4. To carry out a physical medication review monitoring the following on a 12 monthly basis (the patient will be reviewed 6 monthly with reviews alternating between GP 12 monthly review and specialist 12 month review):

    - Height and weight

    - Continued positive impact on sleep (consider discontinuing the medicine to assess continued benefit e.g. 14 day break)

    Results of the above tests should be communicated to the specialist service for reviewing and collating in patient's records: to support this a template is attached as Annex B. After reviewing the monitoring results received the specialist will advise the GP of any required actions.

The practice should communicate to the specialist after every physical medication review. This will enable the specialist to know if the patient is not attending GP follow up which may highlight a safeguarding concern for example.

5. To inform the consultant via the email below if the patient does not attend their 12 monthly physical medication review for advice in particular in relation to appropriate continued prescription.

CCG	CAMHS	Contact number for GPs for advice and guidance	CAMHS Team email
NWS CCG	NW CAMHS (Ashford + St Peters)	0300 222 5755	RXX.SABPCAMHSNW@nhs.net
SD	NE CAMHS (Epsom + Dorking)	0300 222 5755	RXX.SABPCAMHSNE@nhs.net
ES	SE CAMHS (Redhill + Tandridge)	0300 222 5755	RXX.SABPCAMHSSE@nhs.net
GW	SW CAMHS (Guildford and Surrey Heath)	0300 222 5755	RXX.SABPCAMHSSW@nhs.net
SH	SW CAMHS (Guildford and Surrey Heath)	0300 222 5755	RXX.SABPCAMHSSW@nhs.net
NEH and Farmham	Psicon	01227 379099	

6. To record any changes in therapy in the prescribing record on receipt of such communication from secondary care and to act upon these.
7. Refer patients back to the specialist if there is failure to gain weight and height for the expected age and familial characteristics or if there are on-going sleep problems, side-effects or other difficulties.
8. Advise patients to attend their 12 monthly specialist service appointments.
9. Report any adverse drug reactions to the specialist and to the Medicines and Healthcare Products Regulatory Authority (MRHA) as part of the Yellow Card Scheme. https://yellowcard.mhra.gov.uk/

Patient Relatives & Carers

As listed in APC agreed core roles and responsibilities for the shared care of medicines – annex A

Carers should be aware that non-attendance of appointments may result in treatment being stopped.

Key information on the medicine

Please refer to the current edition of the British National Formulary for children (BNF), available at www.medicinescomplete.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication

Insomnia is a widespread problem in children with neurodevelopmental or psychiatric disorders such as autistic spectrum disorder and attention deficit hyperactivity disorder (ADHD).Behavioural therapy can be very effective in some forms of paediatric insomnia however children with neuropsychiatric disorders tend to have a lower response rate to behavioural therapy and may require drug treatment.

Melatonin (N-acetyl-5-methoxytryptamine) is a neurohormone produced by the pineal gland during the dark hours of the day and night which appears to support the normal circadian rhythm and aid sleep onset. It is used as a treatment of sleep disorders in children. It is most helpful where sleep onset is a significant problem, but is rarely useful to maintain sleep if a child is waking during the night. Melatonin should not be used in isolation but should be combined with a behavioural programme, involving Clinical Psychology where necessary.

The use of a weekly sleep diary before and during treatment will assist the monitoring of response.

With regards to its use in children and adolescents with autism spectrum disorders, the British Association for Psychopharmacology guidelines on assessment and treatment of autism spectrum disorder (2017) recommends melatonin, if possible in combination with a behavioural intervention, for the management of sleep disorders in children.

Short term use of melatonin may also occasionally be useful in a range of isolated circumstances where other methods have failed. It should not be considered in the management of sleep problems in otherwise normal children.

Once a regular sleep pattern has successfully been achieved and maintained, there should be a trial withdrawal of treatment. In some children with neurodevelopmental / psychiatric problems, longer term treatment may be needed, but intermittent trials off treatment should be considered.

If tablets cannot be swallowed whole, the licence for some immediate release melatonin (eg Adaflex®) tablets permits crushing of the tablets. The details of the conditions to be treated included in the licence should be confirmed to establish whether this would be an off-label indication

Where the use of a whole or crushed immediate release melatonin tablet is not possible, the use of melatonin oral solution 1mg/mL sugar free (this may be an off-label use) may be considered with due attention paid to the excipients present.

Indication

For the Treatment of Persistent Sleep Disorders in Children 6-17 years old with Attention Deficit Hyperactivity Disorder (ADHD)

Dosage and Administration

- Initiate at melatonin 2mg (formulation selected according to guidance above) 1-2 hours before bedtime.
- Increase dosage according to response. .
- Maximum BNF-C dose 10mg
- If an immediate release preparation is required, the licensed melatonin 1,2,3,4,or 5mg tablets should be prescribed. These may be crushed if required (check licensing of formulation selected).
- If the child wakes during the night, an extra dose of melatonin should not be given.

- **No** other solid dose formulations of melatonin are supported for use

- **No** other liquid formulations of melatonin are supported for use

- Melatonin for use in jet lag is **not** supported for use

- The Slenyto® brand (1mg and 5 mg prolonged release tablets) has been assigned a **NON FORMULARY** status for all indications - see link for further information https://surreyccg.res-systems.net/PAD/Search/DrugConditionProfile/6243

Monitoring

Monitoring requirements including frequency and appropriate dose adjustments	Responsible clinician
Pre-treatment: • Sleep diary	Specialist Clinician
Initiation: • Nil required	
Maintenance: • Monitor continued positive impact on sleep and review every 6 months by discontinuing the medicine to assess continued benefit. • Weight and Growth velocity • Sexual development	Specialist Clinician if ADHD diagnosis; By primary care prescriber if non-ADHD
If dose change when on maintenance: • Nil specific required	

Test	Abnormal Result	Action if Abnormal Result
Effect on sleep	Ineffective at promoting or maintaining sleep	Refer to specialist clinician
Weight, growth velocity, sexual development	Outside normal parameters	Refer to specialist clinician

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Support and Advice for the Primary Care

Name	Speciality	Telephone No.	Email address
Hospital Pharmacy		01483 443717	pharmacy@sabp.nhs.uk
Out of Hours	Via Switchboard	0300 5555 222	

Annex A: APC agreed core roles and responsibilities for the shared care of medicines

Patients

To get the most out of your treatment it's important that you work together with your specialist. You must follow these guidelines to ensure your own safety, health and wellbeing. You should be able to decline shared care If after due consideration of the available options you decide it is not in your best interests.

- You must make sure that you understand about your treatment
- If you do not understand ask for more information from the person prescribing the medicine
- Read the Patient Information Leaflet included with your medication. It will provide you with information about your medication
- You must raise concerns about your treatment with the person prescribing the medicine
- Talk to the specialist and come to an agreement of how the treatment should be provided to you
- Give permission to have aspects of your care communicated to healthcare providers
- **Ensure that you are provided with contact details for support and help if required; both in and out of hours.**
- You must attend all appointments. **Non-attendance of appointments may result in treatment being stopped**
- You must keep a written list of all of the medicines you are taking
- You must keep lists of any additional vitamins, minerals, or other dietary supplements
- You must bring these lists with you each time you visit a healthcare provider or are admitted to a hospital
- You must carry these lists on you in case of an emergency
- You must not let anyone else take your medication.

It is your responsibility to follow these guidelines. The guidelines are here for your safety, health and wellbeing. If you would like more information on your rights, roles and responsibilities in your healthcare please ask a NHS professional for information on the NHS constitution or visit,
www.gov.uk/government/publications/the-nhs-constitution-for-england

Relatives and Carers

As a carer or relative (where it is not possible for the patient to make a decision about future treatment e.g. mental capacity, where possible you should be included in discussions about shared care.

- To support the patient in fulfilling their roles and responsibilities as outlined above.

Consultant/ Specialist

Good Prescribing Guidelines

- Be aware that if you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required (Ref GMC).
- Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required.
- Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the APC with input from specialists and Primary Care Prescribers, and, for individual patients, the patient's Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care.
- Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the patient's CCG
- Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with your Formulary Pharmacist who will facilitate an update via the APC

Before initiating treatment

- Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions.
- Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences
- Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment.
- Undertake baseline monitoring and assessment.

Initiating and continuing treatment in secondary care

- Prescribe initial treatment and provide any associated training and counselling required.
- Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record
- Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable or predictable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
- At any stage of treatment, advising Primary Care Prescriber of concerns regarding monitoring or potential adverse effects of treatment

Transfer of care to Primary Care prescriber

- Liaise with the primary care prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Only advise the patient that shared care will take place, and prescribing will be transferred, once the primary care prescriber has agreed to share responsibility of the patient care, and that this has been confirmed in writing.
- If the primary care prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

Post transfer of care

- Follow up and monitor the patient at appropriate intervals.
- Advise Primary Care Prescriber if treatment dose changes or treatment is discontinued
- Inform Primary Care Prescriber if patient does not attend planned follow-up

Primary Care Prescriber

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the APC as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
- It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).
- Keep yourself informed about all the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely manner.
- Continue prescribing medicine at the dose recommended and undertake monitoring requirements
- Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline
- Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
- Inform the Consultant or specialist of any issues that may arise
- Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g. ensuring the patient record is correct in the event of a patient moving practice).

All

- Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation APC representative who will facilitate an update via the APC.

Annex B: Shared care agreement notification form for medicines and indications approved as amber on the Surrey PAD

Shared Care Agreement for Amber Drugs

For the attention of the Practice Manager and Primary Care Prescriber

Agreement between:

Hospital Information		Practice Information	
Consultant Making Request:		**Primary Care Prescriber Name:**	
Consultant Speciality Details:		**Practice:**	
Consultant email address:		**GP email address:**	

Patient details:

Patient Name:		**Patient DOB:**	Click here to enter a date.
Patient NHS Number:		**Patient's medical practice:**	
Patient Hospital Number:		**GP:**	

Medication details:

Name of medicine:	
Dose:	
Formulation:	
Indication:	
Date next Rx due:	Click here to enter a date.

Please refer to the Surrey PAD (https://surreyccg.res-systems.net/pad/), the Guildford & Waverley and Royal Surrey County Hospital Foundation Trust, joint formulary http://www.guildfordandwaverleyformulary.nhs.uk/ OR Crawley and Horsham & Mid Sussex CCGS, joint formulary http://www.chmsformulary.nhs.uk/, for relevant shared care documents.

It is recommended to read the associated shared care document for this drug prior to acceptance of the agreement.

It is the consultant's responsibility to ensure this shared care agreement has been emailed to the primary care prescriber.

The clinic / discharge letter must be attached to this form and shared with primary care. Please confirm both sender and recipient e-mail addresses are nhs.net before sending to ensure confidentiality.

Agreement to undertake shared care	Choose an item.
If NOT, please state why	

Once complete, please email this form back to the relevant consultant and put a copy in the patient's notes

Appendix C

Sleep Questionnaire

Using these tools will help you and the specialist review your child's sleep and develop the care plan. Complete for two weeks.

Name: DOB: Patient ID/NHS number:	
List any current medications, total daily doses or allergies:	
Do you find that your child has trouble getting off to sleep at bedtime?	Yes/No
Do you find that your child wakes up after bedtime?	Yes/No If yes, how many times?
Does your child have any trouble getting back to sleep when they wake during the night?	Yes/No
Does your child experience any sleepwalking, nightmares (wakes up from a 'bad' dream but can be comforted) or night terrors (waking up screaming/distressed/confused/frightened and difficult to get back to sleep after comforting)?	Yes/No If yes, which ones and what happens?
What time does your child normally go to bed?	School days: Weekends:
What time does your child wake up?	School days: Weekends:
Does your child experience any breathing difficulties (e.g. gasping, pause in breathing) at night?	Yes/No
Do you find that your child snores loudly at night?	Yes/No
Do you think your child has enough sleep?	Yes/No
Do you find that your child has difficulty waking up in the morning?	Yes/No
Do you find that your child is sleepy during the daytime?	Yes/No
Do you find that your child naps during the day?	Yes/No
Do you find that your child tires easily during the day?	Yes/No

With thanks to South West London and St George's Mental Health NHS Trust for sharing this work.

Sleep Diary

Day: **Date:**	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**
Sleepy during the day (Yes/No)							
Duration of any daytime sleep							
Time of any snacking. (e.g. chocolate, fizzy drinks, tea, coffee, sweets)							
Daytime activities							
Activities 1 hour before bedtime							
Time to bed							
Times woke up in the night							
How long did your child stay up for when waking in the night?							
Time awake in the morning							
Mood on waking							
Night time sleep duration							
What did you do to aid your child's sleep? Give a score of 0-5 0 = Did not help 5 = most helpful							