SHARED CARE GUIDELINE FOR MELATONIN

1. Aim/Purpose of this Guideline
   1.1. This guideline applies to medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of melatonin.

2. The Guidance
   2.1. See below for the Shared Care Guideline.
Melatonin is not a licensed product in the UK for this indication. This SCG describes the off label use of the Circadin brand of melatonin and the use of a product unlicensed in the UK.

**INDICATIONS FOR THE PURPOSES OF THIS GUIDELINE**

Sleep disturbances in children with neurological or behavioural disorders are very common. There are multiple factors for this that are frequently interrelated and which include delayed brain maturation, malfunction of sensory organs (particularly vision) and abnormalities or malformation of the sleep centres. The different types of sleep disruption experienced include delayed onset, frequent waking, early morning wakening and reversal of the day-night sleep pattern. These children have a variable response to behavioural therapies and the use of traditional hypnotic or sedative drugs can cause adverse reactions and lead to tolerance and dependence. Melatonin is an endogenous hormone produced by the pineal gland in the brain. The aims of melatonin treatment are to improve the onset and duration of sleep and establish a regular nocturnal sleep pattern. Both CAMHS and the Community Paediatric team will only prescribe melatonin if part of the treatment for comorbid and complex neurodevelopmental disorders.

**PREPARATIONS AND DOSAGE**

Melatonin is available in a range of products. The products to be used locally are:-
- Circadin 2 mg modified release tablets (used off-label in this age group).
- Bio-Melatonin 3mg standard release tablet which can be crushed and dissolved in water. This product should be prescribed by brand name.
- Liquid preparations are no longer recommended. Advice on administration of either product above via a PEG or NG tube can be obtained from RCH Medicines Information.

The specialist teams will consider switching patients to the products described above.

The patient will have received at least two month’s treatment, been shown to respond to the treatment and the dosage stabilised, before prescribing responsibility is transferred to the GP.

**CONTRAINDICATIONS AND PRECAUTIONS**

Melatonin will not be prescribed for:
- Patients aged under 1 year.
- Patients who are pregnant or breast-feeding.
- Patients with sleep disturbances due to obstructive apnoea, emotional distress or nocturnal seizures.
- Patients with severe allergies, auto-immune diseases or immune system cancers. Patients taking immunosuppressants.
- Caution should be exercised when melatonin is used in patients with epilepsy (see below under Side Effects).
- Caution should be exercised when prescribed concomitantly with antidepressants, tranquilizers or other sedatives.
- There is a paucity of clinical data regarding drug interaction with melatonin therefore caution is necessary with all medication.

**MONITORING SPECIALIST TEAM:**
- Responsible for monitoring of growth (both CAMHS and Community Paediatric team) and sexual development (Community Paediatric team).

**GENERAL PRACTICE:**
- There are no specific biochemical monitoring requirements for the GP to undertake.

**SIDE EFFECTS**

- Side-effects are generally unusual and melatonin is generally well tolerated.
- There are some reports of headache, fatigue, confusion, pruritus, hypothermia, tachycardia, nightmares, mild depression, morning grogginess, skin rashes and low sex-drive.
- Other reports suggest that it may cause narrowing of blood vessels in the heart and lungs, especially in patients with underlying heart disease or asthma. Paradoxical wakefulness has been reported. It may also affect serotonin levels.
- In overdose blurred vision and dizziness have been observed and possible nystagmus.
- Based on the known physiological effects of melatonin there could be a potential for inhibition of reproductive functions and delayed puberty. Effects on unborn foetuses or breast-fed children are unknown, but their circadian rhythms could be disturbed.
- There is a known potential for melatonin to affect seizure control in patients with epilepsy. Some reports suggest an improvement, whilst others indicate a worsening of control. The effects of introduction and titration of melatonin in epileptic patients should be closely monitored. There may also be theoretical implications when melatonin is used in conjunction with drugs that lower the seizure threshold.
- Tolerance does not appear to be a problem, but clinicians should remain alert to the possibility.
AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

These are suggested ways in which the responsibilities for the management of patients who are prescribed melatonin can be shared between the specialist and the general practitioners. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and be accepted by them.

In its guidelines on responsibility for prescribing (circular EL(91)127) between hospitals and GPs, the DH has advised that legal responsibility for prescribing lies with the doctor who signs the prescription.

Referral criteria
- A full diagnostic assessment will have taken place under the specialist’s care prior to prescribing melatonin. This will include documented neurological or neurodevelopmental disorder and documented severe, and disrupted, sleep disturbances (failure to respond to desired conventional treatments and problems causing family crises) ideally supported by a 24-hour sleep pattern record covering a minimum of 7-10 days. A sleep pattern record may not be practical or possible for some families.
- The patient will have received at least two month’s treatment (to allow for points 3 and 5 of “Specialist responsibilities” – outlined below) and been shown to respond to the treatment and the dosage stabilised, before prescribing is transferred to the GP.

Specialist responsibilities:
- Make any necessary diagnoses and communicate these to the GP and other professionals involved in the patient’s care.
- Discuss the treatment options with the patient, their parent(s) and carer(s), to include explanation of the unlicensed nature of melatonin, obtaining appropriate consent to treatment and to share care with the GP. A patient information leaflet is attached in Appendix 1 of this document.
- Initiate treatment with melatonin if agreed and titrate the dose to a satisfactory effect over a minimum of 8 weeks.
- Request the GP to take over prescribing in a clear letter; this letter should include full clinical details and document that the unlicensed / off label nature of melatonin has been discussed and consent obtained.
- Ensure the patient has at least 4 weeks supply remaining from the date the GP accepts the request to continue prescribing.
- Ensure the patient is fully aware of the need to arrange a further supply from their GP in a timely manner.
- Offer appointment every 12 months to assess height, weight etc. as necessary. More frequent review may occur if there are other specific problems. CAMHS will keep the patient under review as long as receiving other treatments from that service.
- When appropriate, undertake periodic treatment withdrawals, or advise the GP in writing how and when to undertake them.
- Communicate any changes, recommendations, outcomes or other important information to the GP.
- Provide advice to the GP if they have clinical queries relating to the condition or use of melatonin.
- Take back care of the patient should the GP feel unable to continue to manage the prescribing of melatonin.

General Practitioner responsibilities:
- If the GP agrees to shared care he/she will notify the consultant in writing without undue delay.
- Ensure that the patient, their parent(s) and carer(s) has understood and consented to the off-label / unlicensed use of melatonin. Patient information leaflet is attached in Appendix 1 of this document.
- Accept the request to continue prescribing of melatonin within the boundaries of this shared care protocol – prescribing responsibilities will commence 4 weeks from the date of reply.
- Prescribe appropriate quantities for the patient.
- Carry out further dose titration according to the specified schedule, or discontinue the medication, when necessary or requested.
- Communicate any problems to the Consultant looking after the patient.
- Only ask the Consultant to take back the prescribing should unmanageable problems arise and allow an adequate notice period (4 weeks is a suggested minimum).
- A trial of ceasing melatonin may be undertaken by the GP in discussion with the parent/carer/patient. If the response to stopping treatment is successful, then GP to inform the specialist team who may consider discharging the patient from the service.

Patient: and parent / carer responsibilities
- Agree to request prescriptions from the GP in good time; obtain the first GP prescription within 2 weeks of being informed that shared care will be in operation.
- Report and concerns or adverse effects to the GP, Consultant or Pharmacist.
- Patient information leaflet can be found in Appendix 1 of this document.

BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM THE RELEVANT CLINICAL TEAM
Melatonin – Information for patients, parents and carers

Your child has been prescribed melatonin as the hormone has been shown to improve sleep in children with neurological problems.

Melatonin has been used to treat insomnia (difficulty falling asleep and/or staying asleep). There is a small amount of evidence to suggest that melatonin may also be able to prevent sleep disturbance, such as with jet lag or shift working.

What is melatonin?
Melatonin is a hormone made by a part of the brain called the pineal gland. Melatonin is thought to help our bodies know when it’s time to go to sleep and when it’s time to wake up. Melatonin is now available in the form of a tablet.

How should melatonin be taken?
Your child should be given their dose of melatonin 30-60 minutes before bedtime. Tablets should be swallowed whole with a drink. They can be taken with or without food. If advised by your doctor, Circadin M/R may be crushed, destroying the slow release properties to give an effect that works more quickly. Likewise Bio-Melatonin may be crushed and dispersed in water prior to taking.

The doctor will prescribe an appropriate dose and the dose may be increased at weekly intervals. Most children improve within the first few weeks of treatment.

Does melatonin have any side effects?
Melatonin causes very few side effects. Your child may develop a headache, but this is uncommon. If your child has epilepsy, your doctor will monitor them carefully.

Does melatonin interact with other medicines?
We don’t know if melatonin causes problems when taken with other medicines because this has not been studied.

Does melatonin require a doctor’s prescription?
Yes. This means that the prescribing doctor takes full and complete responsibility for the use of this product in their patient.

How will the melatonin be supplied?
A prescription is taken to your local pharmacy / dispensing surgery and they will be able to obtain supplies of 2mg S/R preparation (Circadin brand) and Bio-Melatonin 3mg standard release which are available via normal routes.

Where can I obtain further information?
You can obtain further information from your consultant.
3. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Compliance with prescribing and administration in accordance with this guideline (or other safe practice)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Head of Prescribing Support Unit</td>
</tr>
<tr>
<td>Tool</td>
<td>No specific tool</td>
</tr>
<tr>
<td>Frequency</td>
<td>As required according to clinical incident reports</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>Via Medicines Practice Committee</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>Relevant Clinical Staff</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>Relevant Clinical Staff</td>
</tr>
</tbody>
</table>

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Diversity & Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment
The Initial Equality Impact Assessment Screening Form is at Appendix 2.
# Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Shared Care Guideline for Melatonin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>September 2016</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>September 2016</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>October 2018</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Paediatric Team, CAMHS M Wilcock, Head of Prescribing Support Unit, Pharmacy Department, RCHT</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 253548</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>Some clinical issues and details of prescribing responsibilities for GP and specialists</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Shared care</td>
</tr>
<tr>
<td></td>
<td>RCHT</td>
</tr>
<tr>
<td></td>
<td>☑</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Date revised:</td>
<td>August 2016</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>Shared care guideline for melatonin V2.1</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Cornwall Area Prescribing Committee</td>
</tr>
<tr>
<td>Divisional Manager confirming approval processes:</td>
<td>Not required</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories:</td>
<td>Governance Lead CSSC</td>
</tr>
<tr>
<td>Signature of Executive Director giving approval:</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet</td>
</tr>
<tr>
<td>Document Library Folder/Sub Folder</td>
<td>Clinical / Pharmacy</td>
</tr>
<tr>
<td>Links to key external standards</td>
<td>None</td>
</tr>
<tr>
<td>Related Documents:</td>
<td>None</td>
</tr>
<tr>
<td>Training Need Identified?:</td>
<td>No</td>
</tr>
</tbody>
</table>
### Version Control Table

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul ‘11</td>
<td>V1.0</td>
<td>Final amendments approved; EIA completed, document published</td>
<td>M Wilcock, Head of Prescribing Support Unit</td>
</tr>
<tr>
<td>Sept’14</td>
<td>V2.0</td>
<td>Updated to comply with latest RCHT format</td>
<td>M Wilcock, Head of Prescribing Support Unit</td>
</tr>
<tr>
<td>July’16</td>
<td>V2.1</td>
<td>Minor amendments to responsibilities</td>
<td>M Wilcock, Head of Prescribing Support Unit</td>
</tr>
</tbody>
</table>

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

**Controlled Document**

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.
Appendix 2. Initial Equality Impact Assessment Screening Form

Name of service, strategy, policy or project (hereafter referred to as policy) to be assessed: Shared care guideline for melatonin

<table>
<thead>
<tr>
<th>Directorate and service area: Pharmacy</th>
<th>Is this a new or existing Procedure?</th>
<th>Existing</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name of individual completing assessment:</th>
<th>Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone:</td>
<td>01726 627953</td>
</tr>
</tbody>
</table>

1. Policy Aim*
To provide information on prescribing of melatonin to enable General Practitioners to take over prescribing responsibility from secondary care.

2. Policy Objectives*
To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area)

3. Policy – intended Outcomes*
Confident and competent prescribers, enabling medicines to be access in a primary care setting.

5. How will you measure the outcome?
If the guideline is not well received, publicised and adopted, then some GPs may not enter into shared care arrangements.

5. Who is intended to benefit from the Policy?
General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.

6a. Is consultation required with the workforce, equality groups, local interest groups etc. around this policy?
No

b. If yes, have these groups been consulted?
c. Please list any groups who have been consulted about this procedure.
Cornwall & IoS Area Prescribing Committee

7. The Impact
Please complete the following table.

Are there concerns that the policy could have differential impact on:

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (male, female, trans-gender / gender reassignment)</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race / Ethnic communities /groups</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Disability - learning disability, physical disability, sensory impairment and mental health problems

Religion / other beliefs

Marriage and civil partnership

Pregnancy and maternity

Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation - this excludes any policies which have been identified as not requiring consultation. or
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended.

Yes ☑ No

9. If you are not recommending a Full Impact assessment please explain why.

Signature of policy developer / lead manager / director

Date of completion and submission

Names and signatures of members carrying out the Screening Assessment

1. Dan Thomas
2. Mike Wilcock

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed _____ Dan Thomas and Mike Wilcock __________

Date _______ Sept 2014 _________