Shared Care Guideline
for
Melatonin in Children and Adolescents for sleep disorders

This shared care guideline (SCG) has been written to enable the continuation of care by primary care clinicians of patients initiated on melatonin by the SWYPFT Barnsley Child and Adolescent Mental health service (CAMHS) and BHNFT Community Paediatrics, where this is appropriate and, in the patients', best interests. Primary care will only be requested to take over prescribing of melatonin within its licensed indication unless specifically detailed otherwise below.

Introduction

Melatonin is a pineal hormone which may affect sleep pattern. Production is affected by light exposure detected by the retina; it is thought that this rhythm is disturbed in children with neurodevelopmental disorders or visual disturbance (European Medicines Agency, 2018).

The prevalence of sleep disturbance in children and adolescents with autistic spectrum disorder (ASD) ranges from 30%–53% and up to 70% in those with attention deficit hyperactivity disorder (ADHD). If untreated, such sleep disturbances can negatively impact children, adolescents, and their families with respect to physical and mental health, social, academic, and cognitive functioning (Sivertsen, 2012). Sleep disturbance may include delayed onset of sleep, frequent waking, and early morning waking or day-night reversal of sleep pattern (Jan, 1994).

NICE summarised that the evidence to support the use of melatonin in children and young people with ADHD is very limited (National Institute for Health and Care Excellence, 2013)). However, clinical experience suggests that when appropriate behavioural sleep interventions fail, melatonin may be of value for treating sleep onset insomnia and delayed sleep phase syndrome in children with conditions such as visual impairment, cerebral palsy, autism, and learning difficulties (Paediatric Formulary Committee, 2022).

Use of Melatonin preparations for conditions outside of the licensed indication in the table below (page 3) is off-label use and requires consent from patient/parent/guardian and documented in the patient notes.
Use of Melatonin preparations for conditions outside of the licensed indication in the table below (page 3) is off-label use and requires consent from patient/parent/guardian and documented in the patient notes.

A trial of melatonin will only be offered if sleep hygiene measures have not been successful*. It is recommended that a minimum of 3 months of behavioural interventions are required before melatonin is offered.*

Sleep hygiene measures should continue alongside the administration of melatonin. Written guidance on sleep hygiene measures should be provided to the carers by the initiating specialist. A useful leaflet can be found on the Research Autism website (http://www.researchautism.net/publicfiles/pdf/good_sleep_habits.pdf). If families cannot implement sleep hygiene measures, then melatonin will not be offered.

When melatonin is prescribed off-license there should be additional information provided to the patient and/or carer by the initiating prescriber, this should be documented within the clinical records. The choice and medication website provides excellent resources:

https://www.choiceandmedication.org/swyp/medication/melatonin/
https://www.choiceandmedication.org/swyp/generate/pillmelatoninsleepadhdcarer.pdf
https://www.choiceandmedication.org/swyp/generate/handyfactsheetunlicensedusesuk.pdf

There were no detectable impact on puberty in a paper by Marlow et al. (Malow, 2021)

Indication

Sleep onset insomnia, delayed sleep phase syndrome, insomnia in patients with learning disabilities, insomnia in children and adolescents aged 6-17 years with ADHD where sleep hygiene measures have been insufficient, insomnia with Autism Spectrum Disorder (ASD) (Slenyto® only), insomnia with Smith-Magenis syndrome (Slenyto® only)

Barnsley Formulary Preparations	**Melatonin Presentation**	**Licensed Indication**	**Formulary Position**	**Additional Information**
	Adaflex® Tablets (AGB-Pharma)(Pharma, 2022) 1mg (£13.30) 2mg (£15.30) 3mg (£17.60) 4mg (£20.23) 5mg (£23.37) Pack size - 30 tablets	Insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient	**First Line** Melatonin preparation for children / adolescents **WITH ADHD** and other indications where an **immediate release formulation** is suitable **(off label use)**	Can be crushed and mixed with water directly before administration Children and adolescents with both ADHD and ASD diagnoses should be prescribed the formulation/s which is /are most cost effective to the needs of the individual. Maximum licensed dose 5mg at night **Doses 6-10mg at night off label use**
	Circadin® prolonged release (PR) Tablets (Flynn Pharma Ltd, 2022) *2mg - £15.39 for 30 tablets (NHSBSA 2022)*	Short term treatment of primary insomnia in patients aged 55 years and over.	**First line** melatonin preparation for children/ adolescents **without** ADHD or ASD and/or Smith-Magenis syndrome and a **prolonged release formulation** is required **(off label use)**	For an immediate release dose First line - Prescribe Adaflex® brand (**off label use**) or: Alternatively halve, quarter or crush Circadin® PR tablets **(off label use).** SWYFT have produced a patient information leaflet which provides advice on crushing: https://www.swyapc.org/wp-content/uploads/2017/01/Advice-on-crushing-Circadin-tablets.pdf Swallowing difficulties For an immediate release dose (crush) – see above. If a prolonged release dose is indicated, consider Slenyto® prolonged release tablets (smaller in size than Circadin®) (**off label use).** Slenyto® tablets can be put into soft food such as yoghurt, orange juice or ice cream to facilitate swallowing. The tablet should not be broken, crushed or chewed because it will lose the PR properties.
	Slenyto® prolonged release (PR) Tablets (Flynn Pharma Ltd, 2021) *1mg - £41.20 for 60 tablets.* *5mg - £103 for 30 tablets (NHSBSA 2020)*	Insomnia in aged 2 -18 years with Autism Spectrum Disorder (ASD) and/or Smith-Magenis Syndrome where sleep hygiene measures have been insufficient.	**Restricted** to children /adolescents with ASD and/or Smith Magenis syndrome (or in other patients with swallowing difficulties as detailed in the additional information section)	For an immediate release dose First line - Prescribe Adaflex® brand (**off label use**) or: Halve, quarter or crush Slenyto® PR tablets **(off label use).** Swallowing difficulties For an immediate release dose (crush) – see above. For a prolonged release dose, tablets can be put into soft food such as yoghurt, orange juice or ice cream to facilitate swallowing. The tablet should not be broken, crushed or chewed because it will lose the PR properties. Children and adolescents with both ADHD and ASD diagnoses should be prescribed the formulation/s which is / are most cost effective to the needs of the individual.

	Consilient Health melatonin 1 mg/ml oral solution* *100ml - £86.67* (Consilient Health, 2022)	Short term treatment of jet lag in adults. Insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient	**Restricted** to children/ adolescents who require medication to be administered via a feeding tube (**off label use**) or in exceptional circumstances in other patients where Adaflex®, Circadin® and Slenyto® have been trialled without success as detailed in the section below**	**Excipients:** glycerol (E422), sorbic acid, methyl parahydroxibenzoate (E218), sodium hydroxide (for pH adjustments) and purified water **Shelf life after first opening: 6 months.**
Barnsley Formulary Preparations (continued)	- At the request of the paediatric consultants the unlicensed option of **Melatonin 3mg MR capsules** (which can be opened and sprinkled on food) has been approved by the APC for restricted use where the licensed/off label alternatives detailed above have been trialled without success and documented. The rationale for the unlicensed Melatonin 3mg MR capsules should be detailed in the shared care request form (appendix A) and patients should have ongoing reviews by paediatrics as to the suitability of the formulation. - **At the request of the initiating prescriber the use of **Consilient Health Melatonin 1mg/ml oral solution** has been approved by the APC for restricted use in patients without enteral feeding tubes where the other licensed/off label preparations detailed above have been trialled without success and documented. The rationale for the use of Consilient Health Melatonin 1mg/1ml oral solution should be detailed in the shared care request form (appendix A) and patients should have ongoing reviews by the specialist as to the suitability of the formulation. **Due to the growing number of melatonin formulations coming to market, melatonin should be prescribed by brand name in secondary care to avoid confusion.** **Other melatonin preparations not included in the above table are non-formulary.** Patients currently prescribed preparations not listed in the table above should be reviewed and if there is a continued need for melatonin, switched to a preparation within the table, using a licensed/off label preparation where available			

Dosage and Administration - Most patients respond at doses of 6mg or less (Horman, 2019)

Adaflex ® tablets (standard release)

Problems with sleep initiation

The recommended starting dose is 1-2 mg 30-60minutes before bedtime; the dose can be increased by 1 mg every week until effect up to a maximum 5 mg per day, independent of age; the lowest effective dose should be sought.

Doses between 6-10mg are off label use.

It is recommended that food is not consumed 2 h before and 2 h after intake**.**

Problems with sleep maintenance or early morning waking

If Adaflex® is ineffective then modified release melatonin is indicated. Circadin® 2mg prolonged release tablets should be prescribed, to be swallowed whole 60-90 minutes prior to bedtime.

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

If Adaflex® is ineffective then modified release melatonin is indicated. Circadin® 2mg prolonged release tablets should be prescribed, to be swallowed whole 60-90 minutes prior to bedtime

In some children a combination of immediate release (i.e. Adaflex® or Circadin® quartered, halved or crushed tablets) and whole tablets of Circadin® may be required, up to a maximum total dose of 10mg.

Another strategy to consider is giving a whole Circadin® tablet earlier in the evening and another dose at bedtime for help with sleep initiation and maintenance.

Circadin ® 2mg modified release tablets

Problems with sleep initiation

A standard release melatonin is indicated, see Adaflex® above.

Alternatively, this can be obtained by quartering, halving or crushing Circadin® 2mg prolonged release tablets.

The starting dose is usually 2mg given 30 minutes before bedtime. If there is no response or an insufficient response after a minimum of 14 days therapy the dose is increased by 2mg. If further increases in dose are needed these should be made after a minimum of 14 days on each dose, in 2mg increments. In certain circumstances the dose can be increased up to a maximum dose of 10mg.

Problems with sleep maintenance or early morning waking

Modified release melatonin is indicated in the first instance. Circadin® 2mg prolonged release tablets should be prescribed, to be swallowed whole 60-90 minutes prior to bedtime.

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

A prolonged release preparation (Circadin®) is indicated. In some children a combination of immediate release (Adaflex® or quartered, halved or crushed Circadin® tablets) and whole tablets of Circadin® may be required, up to a maximum total dose of 10mg.

Another strategy to consider is giving a whole Circadin® tablet earlier in the evening and another dose at bedtime for help with sleep initiation and maintenance.

Slenyto ® 1mg and 5mg modified release tablets

Treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient

The recommended starting dose is 2 mg daily. If an inadequate response has been observed, the dose should be increased to 5 mg, with a maximal dose of 10 mg.
Slenyto® should be taken once daily, 0.5-1 hour before bedtime and with or after food.
Up to 2 years treatment is included in the product license and there is limited safety data with melatonin beyond this.

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

A prolonged release preparation (Slenyto®) is indicated. In some children a combination of immediate release (i.e. Adaflex® or quartered, halved or crushed Circadin® tablets) and whole tablets of Slenyto® may be required, up to a maximum total dose of 10mg.

Another strategy to consider is giving a whole Slenyto® tablet earlier in the evening and another dose at bedtime can help with sleep initiation and maintenance

Consilient Health Melatonin 1mg/1ml oral solution

Only recommended when patients require medication administered by an enteral feeding tube or in the exceptional circumstances detailed in the previous 'Barnsley Formulary Preparations' section of the document. Please consider tablet forms above as detailed before considering oral solution.

Insomnia in children and adolescents (6-17 years of age) with attention deficit hyperactivity disorder (ADHD) where healthy sleeping routines has not worked well enough.

1-2 ml (equivalent to 1 to 2 mg) 30-60 minutes before bedtime. Maximum recommended daily dose: 5 ml (equivalent to 5 mg). The dose will be adjusted individually to a maximum of 5 ml (equivalent to 5 mg) daily, regardless of age. The lowest dose possible will be given.
Limited data are available for up to 3 years of treatment.

Sleep disorders for indications other than ADHD

As above (off label)
Doses between 6-10mg (off label use)

Responsibilities of the specialist clinician initiating treatment

Summary

- To assess the suitability of the patient for treatment and initiate melatonin in appropriate patients. (including confirming the patient has no contra-indications to treatment and considering the relevance of any cautions, including interactions).
- To discuss the benefits and side effects of treatment with the patient/carer and the need for long term monitoring if applicable. Obtain informed consent in line with national guidance. This is particularly important for unlicensed products. To discuss the patient's responsibilities (see relevant section) in relation to the shared care agreement.
- To perform baseline tests and if appropriate routine tests until the patient is stable (see details of baseline and routine tests which should be carried out by the specialist in the monitoring section below).
- To prescribe for the first 12 weeks of treatment (include if the specialist will review the patient after initiation before prescribing is picked up in primary care).
- To ask the GP whether they are willing to participate in shared care.
- To provide the GP with a summary of information relating to the individual patient to support the GP in undertaking shared care (see shared care request form in Appendix A which includes a link to the shared care guideline).
- To advise the GP of any dosage adjustments required, monitoring required, when to refer back, and when and how to stop treatment (if appropriate).
- To advise the GP when the patient will next be reviewed by the specialist but if ongoing specialist co-ordination of the patient's care is not required, an individual care plan should be agreed on a case-by-case basis. This may include the access to advice and intervention of that specialist in a timelier manner than via a new referral and may fall outside shared care arrangements.
- To monitor the patient for adverse events and report to the GP and where appropriate Commission on Human Medicines/MHRA (Yellow Card scheme).
- To provide the GP with contact details in case of queries.
- To provide patient / carer with contact details for support and help if required; both in and out of hours.

Responsibilities of the primary care clinician

Acceptance of Responsibility by the Primary Care Clinician

It is optional for the primary care clinician to participate in taking on responsibility for shared care for the patient. Primary care clinicians will take on shared care only if they are willing and able.

Summary

- To reply to the request for shared care as soon as possible.
- To prescribe and adjust the dose as recommended by the specialist.
- To ensure there are no interactions with any other medications initiated in primary care.
- To continue monitoring as agreed with secondary care in the monitoring section below.
- To inform the specialist if the patient discontinues treatment for any reason.
- To seek the advice of the specialist if any concerns with the patient's therapy. For example:
  - Patient or general practitioner is **not** comfortable to continue with the existing regime due to either change in condition or drug side effects.
  - Advice in respect of concordance.
  - Special situations, (e.g. Pregnancy).
- Discontinue the drug as directed by the specialist if required.
- To conduct an annual medication review or more frequently if required.
- To identify adverse events if the patient presents with any signs and liaise with the hospital specialist where necessary. To report adverse events to the specialist and where appropriate the Commission on Human Medicines/MHRA (Yellow Card scheme).

Responsibilities of Patients or Carers

Summary

- To be fully involved in, and in agreement with, the decision to move to shared care.
- To attend hospital and primary care clinic appointments and to bring monitoring information e.g. booklet (if required). Failure to attend will potentially result in the medication being stopped.
- Present rapidly to the primary care prescriber or specialist should the clinical condition significantly worsen.
- Report any suspected adverse effects to their specialist or primary care prescriber whilst taking melatonin.
- To read the product information given to them.
- To take melatonin as prescribed.
- Inform the specialist, primary care prescriber or community pharmacist dispensing their prescriptions of any other medication being taken – including over-the-counter medication.

Clinical Particulars

The details of side-effects, cautions, contraindications and interactions are not a complete list and the current BNF (https://www.medicinescomplete.com/#/) and the SPC (https://www.medicines.org.uk/emc/) remain authoritative.

BNF therapeutic class	Non-benzodiazepine hypnotics and sedative drugs
Cautions and Contraindications	Hypersensitivity to melatonin or to any of the excipients listed within the preparation. Not recommended for use in patients with autoimmune diseases. Some preparations contain lactose, patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption. There is no experience of the use of Melatonin in patients with liver impairment. Therefore, Melatonin is not recommended for use in patients with hepatic impairment. The effect of any stage of renal impairment on Melatonin pharmacokinetics has not been studied. Caution should be used when Melatonin is administered to patients with renal impairment. Little is known about the long-term implications of melatonin use in children especially in relation to the impact it may have on other circadian rhythms including endocrine or reproductive hormone secretion (paediatric formulary committee 2019)
Pregnancy and breast feeding	No information available – avoid Present in milk - avoid
Adverse Drug Reactions	Melatonin is generally well tolerated. Adverse effects of melatonin include: **Common or very common:** Arthralgia, headaches, increased risk of infection, pain. **Uncommon:** Anxiety; asthenia; chest pain; dizziness; drowsiness; dry mouth; gastrointestinal discomfort; hyperbilirubinemia; hypertension; menopausal symptoms; mood altered; movement disorders; nausea; night sweats; oral disorders; skin reactions; sleep disorders; weight gain. **Rare or very rare:** Aggression; angina pectoris; arthritis; impaired concertation; crying; depression; disorientation; electrolyte imbalance; excessive tearing; gastrointestinal disorders; haematuria; hot flushes; hypertriglyceridemia; leukopenia; memory loss; muscle complaints; nail disorder; palpitations; paraesthesia; partial complex seizure; prostatitis; sexual dysfunction; syncope; thirst; thrombocytopenia; urinary disorders; vertigo; vision disorders; vomiting. **Frequency not known:** Angioedema; galactorrhoea. Full details can be found in the manufacture's summary of product characteristics and the patient information leaflets. Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme: www.mhra.gov.uk/yellowcard

Monitoring	Treatment duration is intended to be as short as possible. It is important that patients continued need for treatment is reviewed at appropriate intervals (Horman, 2019). While the initiating specialist will retain for overall responsibility for the monitoring, GP's who have an interest or feel competent to do so can use the guideline below to manage their shared care patients in primary care *. **Treatment Targets** (Espie, 2012) 1. **Sleep Latency reduced by at least 30minutes** 2. **Longest Sleep Period increased by at least 45minutes** 3. **Total sleep time increased by at least 45 minutes** **After 3 months treatment (specialist)** • If response is achieved and decision to continue, consider transfer of prescribing to GP under shared care arrangement. **After 6 months treatment (specialist or GP)** • Attempt withdrawal over a period of 3-4 weeks, with observation of changes to sleep pattern. **6-monthly thereafter (specialist or GP)** • Monitor for a possible impact of melatonin on their pubertal development and other adverse effects. • Review the continued need for and effectiveness of melatonin. • Consider a trial withdrawal or dose reduction of treatment (over 3-4 weeks) • Continue to support behavioural methods of good sleep hygiene. **After 2 -3 years (specialist)** • Efficacy and safety data are not available beyond two years treatment. Do not continue melatonin beyond 2-3 years unless the specialist has authorised. **Melatonin Formulation Review (Specialist or Primary Care)** • For those prescribed an unlicensed formulation (e.g. melatonin 5mg/5ml oral solution) or a Melatonin preparation that is not in line with the Barnsley formulary, if continued need for melatonin identified, determine whether a switch to a licensed product (or licensed product used off-label) can meet patient needs (e.g. Adaflex ®/Circadin® / Slenyto®) in line with the agreed formulary. *If the GP **makes changes** then please liaise with the specialist to avoid duplication **STOPPING TREATMENT** • It should be made clear to parents and carer at initiation that the treatment is intended for short term use. • An attempt to withdraw/have a break in treatment should be considered at least annually. • Those on lower doses (2-4mg) may be withdrawn without downwards titration, higher doses (6-10mg) may require a period of dose reductions. Attempted withdrawal is usually over a period of 3-4 weeks, with observation of changes to sleep pattern. • Sleep hygiene should be reinforced throughout treatment and prior to any attempt to stop. • Carer to complete sleep diary before, during and upon re-starting from treatment break. Mobile apps such as SnappD may be helpful. • Treatment may be stopped by GP or specialist. • 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 1-2mg daily using a licensed preparation where possible, increasing by 1-2mg each week if required Doses above 4-6mg are rarely required. Total daily dose should not exceed 10mg daily or the maximum of previous dose agreed by specialist.

Interactions	Interaction studies have only been performed in adults. In the absence of specific studies in children, the drug interactions with melatonin are those known in adults. Melatonin's metabolism is mainly mediated by CYP1A enzymes. Therefore, interactions between melatonin and other active substances as a consequence of their effect on CYP1A enzymes is possible. **Concomitant use not recommended** Concomitant use of the following medicinal products is not recommended: *Fluvoxamine* Fluvoxamine increases melatonin levels (by 17-fold higher AUC and a 12-fold higher serum C_{max}) by inhibiting its metabolism by hepatic cytochrome P450 (CYP) isozymes CYP1A2 and CYP2C19. The combination should be avoided. *Alcohol* Alcohol should not be taken with melatonin, because it reduces the effectiveness of melatonin on sleep. *Benzodiazepines/non-benzodiazepine hypnotics* Melatonin may enhance the sedative properties of benzodiazepines and non-benzodiazepine hypnotics, such as zaleplon, zolpidem and zopiclone. In a clinical trial, there was clear evidence for a transitory pharmacodynamic interaction between melatonin and zolpidem one hour following co-dosing. Concomitant administration resulted in increased impairment of attention, memory and co-ordination compared to zolpidem alone. Combination with benzodiazepines and non-benzodiazepine hypnotics should be avoided. *Thioridazine and imipramine* Melatonin has been co-administered in studies with thioridazine and imipramine, active substances which affect the central nervous system. No clinically significant pharmacokinetic interactions were found in each case. However, melatonin co-administration resulted in increased feelings of tranquility and difficulty in performing tasks compared to imipramine alone, and increased feelings of "muzzy-headedness" compared to thioridazine alone. Combination with thioridazine and imipramine should be avoided. **Concomitant use to be considered with caution** Concomitant use of the following medicinal products should be considered with caution: *5- or 8-methoxypsoralen* Caution should be exercised in patients on 5- or 8-methoxypsoralen (5 or 8-MOP), which increases melatonin levels by inhibiting its metabolism. *Cimetidine* Caution should be exercised in patients on cimetidine which is a potent inhibitor of certain cytochrome P450 (CYP450) enzymes, mainly CYP1A2 and thereby increases plasma melatonin levels, by inhibiting its metabolism. *Oestrogens* Caution should be exercised in patients on oestrogens (e.g. contraceptive or hormone replacement therapy), which increase melatonin levels by inhibiting its metabolism by CYP1A1 and CYP1A2. *CYP1A2 inhibitors* CYP1A2 inhibitors such as quinolones (ciprofloxacin and norfloxacin) may give rise to increased melatonin exposure. *CYP1A2 inducers* CYP1A2 inducers such as carbamazepine and rifampicin may reduce plasma concentrations of melatonin. Therefore, when CYP1A2 inducers and melatonin are both given, dose adjustment may be required. Smoking Smoking is known to induce CYP1A2 metabolism, therefore if patients stop or start smoking during treatment with melatonin, dose adjustment may be required. NSAIDs Prostaglandin synthesis inhibitors (NSAIDs) such as acetylsalicylic acid and ibuprofen, given in the evening may suppress endogenous melatonin levels in the early part of the night by up to 75%. If possible, administration of NSAIDs should be avoided in the evening. Beta-blockers Beta-blockers may suppress the night-time release of endogenous melatonin and thus should be administered in the morning

Additional information	• Add link to sleep hygiene document when available • Other useful online sleep resources (behavioural strategies and sleep diaries): • **Home - The Sleep Charity** • **Sleep Advice Service - Cerebra** • **https://www.autism.org.uk/advice-and-guidance/topics/physical-health/sleep/parents** • **Let's Sleep (letssleep.org)**
Re-Referral guidelines	• Please contact CAMHS 01226 644829 or Community Paediatrics 01226 644872
Ordering information	• Not applicable

Communication and contact details

Specialist to primary care clinician
The specialist will inform the primary care clinician when they have initiated melatonin. When the patient is near completing the satisfactory initiation period, the specialist will write to the primary care clinician to request they take over prescribing and where possible give an indication as to the expected length of treatment. The specialist will also send a shared care request form to support the primary care clinician in undertaking shared care. (Appendix A)

Primary Care Clinician to specialist
If the primary care clinician has concerns over the prescribing of melatonin, they will contact the specialist as soon as possible.

Contact names and details

Contact Details	**Telephone number**	**Email**
Child and Adolescent Mental Health Service		
Dr Niloufar Mirhaghani, Consultant Psychiatrist	01226 644829	Niloufar.Mirhaghani@swyt.nhs.uk
Dr Lourence Lewis-Hanna, Consultant Psychiatrist	01226 644829	Lourence.Lewis-Hanna@swyt.nhs.uk
Dr. Ovidiu Sandica , Consultant Psychiatrist	01226 644829	Ovidiu.Sandica@swyt.nhs.uk
Dr Andrew Charters, Consultant Psychiatrist	01226 644829	Andrew.charters@swyt.nhs.uk
Dr Hillary Reed, Specialty Doctor	01226 644829	Hilary.Reed@swyt.nhs.uk
Dr Marco Haring, Specialty Doctor	01226 644829	Marco.Haring@swyt.nhs.uk
Dr Aly Middleton, Specialty Doctor	01226 644829	Aly.middleton@swyt.nhs.uk
Dr Jo Perera, Speciality Doctor	01226 644829	Joanne.perera@swyt.nhs.uk
Jo Newing, ADHD Advanced Nurse NMP	01226 644829	Jo.Newing@swyt.nhs.uk
Rebecca Pycko, ADHD Advanced Nurse NMP	01226 644829	Rebecca.Pycko@swyt.nhs.uk
Katie Crowe, Advanced Clinical Pharmacist NMP	01226 644829	Katie.crowe@swyt.nhs.uk
Community Paediatrics		
Dr Jaya Dixit	01226 644872	Jaya.dixit1@nhs.net
Dr Andrea Nussbaumer	01226 644872	andrea.nussbaumer@nhs.net
Dr Angela Oliver	01226 644872	angela.oliva2@nhs.net
Dr Shobha Sivaramakrishnan	01226 644886	Shobha.sivaramakrishnan@nhs.net
Dr Mahmud Tumi	01226 644876	mtumi@nhs.net
Dr Fiona Blyth	01226 644868	fionablyth@nhs.net
Dr Limyaa Mohamed	01226 644876	limyaa.mohamed1@nhs.net
Terrie Mcniffe, Specialist Neurodisability Nurse		terrie.mcniffe@nhs.net
Andrea Robinson, Specialist Neurodisability Nurse		Andrea.robinson7@nhs.net

Equality and diversity

- Not applicable

References

Consilient Health. (2022). Consilient Health Melatonin 1mg/1ml oral solution. Retrieved June 16, 2022, from Summary of Product characteristics website: https://www.consilienthealth.co.uk//wp-content/uploads/2022/05/uk-spc-appr-18.03.2022.pdf

Espie, C. M. M. and C. A. (2012). *Oxford Handbook of Sleep and Sleep Disorders*. THE OXFORD LIBRARY OF PSYCHOLOGY.

European Medicines Agency. (2018). Committee for medicinal products for human use (CMHP) Slenyto assessment report. Retrieved from https://www.ema.europa.eu/en/documents/%0Aassessment-report/slenyto-epar-public-assessment-report_en.pdf

Flynn Pharma Ltd. (2021). Slenyto 1mg Prolonged release Tablets. Retrieved from Electronic Medicines Compendium website: https://www.medicines.org.uk/emc/product/10023

Flynn Pharma Ltd. (2022). Circadin 2mg Prolonged release tablets. Retrieved from Electronic Medicines Compendium website: https://www.medicines.org.uk/emc/product/2809

Horman, K. (2019). PresQuipp bulletin. Melatonin. Retrieved from Prescqipp Community Interest Company website: https://www.prescqipp.info/media/4586/245-melatonin-21.pdf

Jan, J. E. (1994). The treatment of sleep disorders with melatonin. *Dev Med Child Neurol*, *36*, 97–107.

Malow, B. A. (2021). Sleep, Growth, and Puberty After 2 Years of Prolonged-Release Melatonin in Children With Autism Spectrum Disorder. *J Am Acad Child Adolesc Psychiatry* ., *60*(2), 252–261. Retrieved from https://pubmed.ncbi.nlm.nih.gov/31982581/

National Institute for Health and Care Excellence. (2013). Sleep disorders in children and young people with attention deficit hyperactivity disorder: melatonin [ESUOM2]. Retrieved from National Institute for Health and Care Excellence website: https://www.nice.org.uk/advice/esuom2/chapter/Key-points-from-the-evidence

Paediatric Formulary Committee. (2022). BNF for children. Retrieved from MeReC Extra website: https://bnfc.nice.org.uk/

Pharma, A. (2022). Adaflex 1mg Tablets. Retrieved from Electronic Medicines Compendium website: https://www.medicines.org.uk/emc/product/13628

Sivertsen, B. (2012). Sleep problems in children with autism spectrum problems: a longitudinal population-based study. *Autism*, *16*(2), 139–150.

https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

Development Process

This guidance has been produced following an AMBER classification status of melatonin by the Barnsley Area Prescribing Committee. This guideline was ratified by the Area Prescribing Committee on 12th October 2022.

Appendix A – Shared Care request form (Amber) for [insert drug name or clinical area]

- Specialist to complete when requesting primary care clinician to enter a shared care arrangement.
- Primary care clinician to return signed copy of form. [Insert details of how to return the form e.g. to a safe haven e-mail address, postal address if the form should be returned by post]
- Both parties should retain a signed copy of the form in the patient's record.

From (**Specialist**): _____ **To** (**Primary care clinician**): _____

As per the agreed Barnsley shared care guideline for melatonin, this patient is now suitable for prescribing to move to primary care.

The patient fulfils the criteria for shared care and I am therefore requesting your agreement to participate in shared care. I have carried out baseline tests and initial monitoring as detailed in the shared care guideline.

Patient details

Name: _____ NHS Number: _____

Address: _____ DOB: _____
Diagnosed condition: _____

Amber Drug details

Drug name (please indicate): Adaflex / Circadin / Slenyto / Consilient Health Melatonin 1mg/1ml oral solution* / Unlicensed Melatonin MR 3mg capsules* (paediatrics only)
*rationale to be indicated
Dose and frequency: _____
Date of initiation: _____ Length of treatment: _____

The patient has been provided with sufficient medication to last until: _____
The patient will be reviewed by the consultant / prescriber on: _____
The patient should be reviewed by the primary care clinician by: _____

Monitoring

The following monitoring should be undertaken by the primary care clinician. Refer to the monitoring section of the shared care guideline.

Parameter	Date next test due	Frequency

Communication

Consultant
Telephone number: _____ Fax number:_____

Email address: _____

Specialist Nurse/Prescriber
Telephone number: _____ Fax number: _____

Email address: _____

Confirmation of acceptance of shared care

Specialist (Doctor/Nurse) name: _____

Specialist (Doctor/Nurse) signature: _____ Date: _____

I, [insert name of primary care clinician] can confirm I :

☐ accept the request to participate in shared care for the patient named above and will complete the monitoring as set out in the shared care guideline for this medicine/condition.

☐ reject the request to participate in shared care for the patient named above. The reason for this being ……

Signature of primary care clinician: _____Date:_____

To save resources you have been sent appendix A of the shared care document. The full document (*Melatonin SCG, date approved October 2022)* can be accessed on the Barnsley BEST website at the following link:
http://best.barnsleyccg.nhs.uk/clinical-support/medicines/shared-care-guidelines/
Or via the Barnsley Area Formulary www.barnsleyformulary.nhs.uk