CLINICAL GUIDELINE

Melatonin prescription for Acute and Chronic Insomnia in adults

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The online version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as ‘Uncontrolled’ and as such, may not necessarily contain the latest updates and amendments.

NHS Greater Glasgow and Clyde

OBJECTIVE OF GUIDELINE

This guideline describes the processes and agreement in relation to the prescription of melatonin for acute and chronic insomnia for adults within NHSGGC. It aims to ensure that melatonin is appropriately recommended for prescription and monitored within secondary care, with subsequent safe discharge and follow up through primary care.

Note that NHSGGC do not have a designated Sleep Service for adults. This guideline does not support referral from primary to secondary care solely for the purpose of insomnia or melatonin prescription. Rather, it is to allow the safe and appropriate prescription of melatonin by secondary care as part of a wider treatment (for example Sleep Apnoea or as part of the treatment of psychiatric illness.) The only exception to this is Specialist Learning Disability Services, who will sometimes consider referrals for insomnia (due to the high frequency of Sleep Disorders and high potential impact on carers in this population.)

BACKGROUND

Although formal evidence is limited, there is increasing positive experience of the prescription of melatonin for sleep disorders, particularly for patients with neurodevelopmental disorders. Melatonin is now widely prescribed within Children's Services in NHSGCC, and increasingly used within Adult Services including Mental Health services (particularly Learning Disability Services) and Sleep Medicine services. Melatonin is generally a safe medication with few interactions and side effects. This is reflected in the most recent BAP Guidelines (BAP 2019).

Melatonin is very well tolerated, and does not require specific physical monitoring. Previous NHSGGC guidance recommended long term follow up through secondary care, but given the low risks and lack of evidence for long term monitoring, this guideline supports initiation following recommendation by secondary care with longer term prescription and monitoring by primary care through usual medication review processes.

SCOPE

These guidelines are to be used by:

- Specialist Services responsible for recommending the initiation of melatonin prescription (including Sleep Medicine, Neurology, Mental Health and Learning Disability)

- Primary care responsible for long term prescription and review

These guidelines only cover adults (aged 18+). The existing Shared Care Agreement between Primary Care and Specialist Services remain in place for children and young adults.

ROLES/RESPONSIBILITIES

All doctors are expected to prescribe within their competency.

Doctors in Specialist Services recommending melatonin initiation are expected to have the required competencies and experience to ensure safe prescription of melatonin. This should be achieved through the usual processes (including Core and Higher Training programmes, CPD, and supervised clinical experience).

Doctors continuing ongoing prescription of melatonin in Primary Care do not require any additional experience or competencies.

INITIATION OF MELATONIN

Melatonin should only be initiated following recommendation by secondary care. Melatonin is included in the NHSGGC Adult Medicines Formulary as "'Melatonin should only be initiated on the recommendation of secondary care'".

Melatonin should be prescribed in accordance with licensed and other appropriate uses as outlined below. It should not be prescribed out with these parameters.

- Insomnia (short term use for up to 13 weeks) – Licensed use (modified-release tablets, adult 55 years and over)
- Insomnia in patients with learning disabilities and challenging behaviour
- REM behaviour disorder
- Circadian rhythm disorders
- Sleep behaviour disorder
- Adjunct in parasomnias or sleep disorders with sleep fragmentation

Jet lag is now a licensed indication for melatonin. However, melatonin for this purpose would be classified as a medicine used for travel or in anticipation of an ailment occurring overseas. Primary care should therefore not provide an NHS prescription for this.

Melatonin should be prescribed in generic form. Approved medicinal forms include:

- Melatonin 2mg modified-release tablets
- Melatonin 3mg immediate-release tablets
- Melatonin 1mg in 1ml oral solution

RESPONSIBILITIES OF SPECIALIST SERVICES

- Assess the suitability of patients for treatment
- Recommend initiation and monitor until the patient is stabilized on an appropriate dose and preparation
- Assess and monitor patient's response to treatment and discontinue if ineffective
- Seek informed consent from the patient or carer for this prescribed therapy ensuring an understanding of potential side effects
- Provide an initial letter to the General Practice team including diagnoses, indication for use, relevant clinical information, treatment plan, dose of melatonin and duration of treatment plan before specialist review

DISCHARGE TO PRIMARY CARE

On discharge from Specialist Services, if melatonin is to be continued a letter should be provided to the General Practice team providing robust information on the following:

- Ongoing treatment plan
- Anticipated length of treatment, including whether melatonin should be discontinued at 13 weeks or whether it should be continued long term.
- Advice around review. Given that no specific monitoring is required, this would usually be to continue melatonin whilst there is ongoing benefit, and otherwise to discontinue
- Clear guidance regarding de-prescribing
- Information in relation to 'patient initiated return' or whether primary care may re-institute a previously agreed prescription without re-referral to secondary care
- Options for further specialist advice or review

RESPONSIBILITIES OF PRIMARY CARE (GENERAL PRACTICE TEAM)

Primary Care should refer patients to the appropriate Specialist Service in line with existing referral criteria (i.e. for the assessment and treatment of suspected Sleep Apnoea, Severe and Enduring Mental Illness and Neurological disease). With the exception of Specialist Learning Disability Services, referrals will not be accepted for the assessment and treatment of insomnia, or for the prescription of melatonin. Specialist Learning Disability Services will only consider referrals for severe insomnia where this has a significant impact on the patient or carer. (The first line treatment offered will be behavioural support from Learning Disability Nursing).

Once the patient has been accepted and assessed by Specialist Services, the role of Primary Care is to:

- Prescribe melatonin to support the specialist recommendation
- Continue to prescribe melatonin as outlined by the specialist service
- Review melatonin as part of usual medication review processes in practice
- Seek specialist clinical advice or review where appropriate

TRANSITION OF PATIENTS FROM CHILDREN'S SERVICES

Melatonin is often initiated by Children's Services. At present, there is no agreement that children and young adults on melatonin can be discharged and followed up by primary care. Melatonin should be prescribed in line with the existing Shared Care Agreement and Children's Services should hold onto all patients requiring ongoing melatonin prescription until they reach the age of 18.

At the time of transition, we recommend that patients should have a full review, including a review of their medication and ongoing requirement for specialist input. If the patient has reached the age of 18 and is stable on melatonin (and does not have any other requirement for Specialist Services), we advise that the patient is discharged to Primary Care and that their discharge letter contains the same robust information as above. This will allow the General Practice team to manage the patient in line with this guidance.

Initial queries around discharge should be directed to Children's Services. However, Children's Services are unable to provide care for adults and discharge advice should therefore be provided in relation to which adult service would be appropriate to contact should specialist clinical advice or review be required.

REFERENCES

British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders: An update. Wilson, S., Anderson, K. et al., Journal of Psychopharmacology, 2019, Vol. 33 (8) 923-947