

Kent and Medway Policy Recommendation and Guidance Committee Policy Recommendation

Policy:	PR 2021-01: Melatonin for jet lag
Issue date:	March 2021

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered UK legislation, national and professional society guidance, NICE CKS, the baseline position, other CCG policies and the potential impact of changing policy. All decisions were made with reference to the Ethical Framework. Taking these into account the PRGC recommends:

• Melatonin is not routinely funded for the management of jet lag.

This policy recommendation will be reviewed when new information becomes available that is likely to have a material effect on the current recommendation.

Kent and Medway Clinical Commissioning Group (CCG) will always consider appropriate individual funding requests (IFRs) through its IFR process.

Supporting documents

NEL Health Policy Support Unit (HPSU) (2021) Melatonin for jet lag – Briefing note

Equality Analysis Screening Tool – Melatonin for jet lag (2021)

Key points

What is jet lag?

Jet lag commonly affects air travellers who cross several time zones rapidly. It results from the body's internal rhythms being out of step with the day-night cycle at the destination.

Typical symptoms of jet lag are sleep disturbances and daytime tiredness and fatigue, though mild cognitive impairment, irritability, and gastrointestinal disturbances may also occur. Jet lag is worse the more time-zones crossed, and is typically worse following eastward travel as people generally find it harder to advance their circadian rhythm (body clock) than to delay it, as required following westward travel.

According to <u>NHS.uk</u>, medicines are not usually needed for jet lag. Jet lag usually improves within a few days as the body adjusts to the new time zone. The NHS website also states that melatonin tablets are not recommended for jet lag because there's not enough evidence to show they work.

What is melatonin?

Melatonin is a naturally occurring hormone produced by the pineal gland in the brain. It is involved in coordinating the body's sleep-wake cycle and helping to regulate sleep.

A licensed melatonin preparation (i.e. Circadin) for use in adults aged ≥55 years for the short-term treatment of primary insomnia has been available since 2008. Two new formulations are now licensed for the short-term treatment of jet lag in adults; melatonin 3mg film-coated tablets and melatonin 1mg/ml oral solution (both Colonis Pharma Ltd). They are prescription only medicines (POMs) and so cannot be purchased over the counter (OTC).

What does UK legislation say?

Melatonin used for jet lag would be classified as a medicine used for travel and in anticipation of an ailment. GPs are not responsible for providing NHS prescriptions for conditions which may arise while abroad or travelling¹. If wanted, GPs may issue private prescriptions for their patients for melatonin in anticipation of jet lag.

What does NICE say?

- There is no NICE technology appraisal guidance on the use of melatonin and no clinical guidelines on the management of jet lag
- NICE CKS² on jet lag (2019) does not recommend the use of melatonin to promote sleep in jet lag in primary care as there is limited and conflicting evidence of benefit

What does other national guidance say?

The <u>AWMSG³</u> does not endorse the use of melatonin 1mg/ml oral solution or 3mg tablets (both Colonis Pharma Ltd) within NHS Wales for the short-term treatment of jet lag in adults because the company has not made a submission to AWMSG regarding this product (2019)

What does professional society guidance say?

According to the <u>British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders</u> (2019), melatonin may be useful in jet lag disorder.

¹ The <u>National Health Service (General Medical Services Contracts) Regulations 2015</u> (accessed 03/03/21) states that GPs may demand or accept (directly or indirectly), a fee or other remuneration for prescribing or providing drugs, medicines or appliances (including a collection of such drugs, medicines or appliances in the form of a travel kit) which a patient requires to have in their possession solely in anticipation of the onset of an ailment or occurrence of an injury while that patient is outside of the UK but for which that patient is not requiring treatment when the drug, medicine or appliance is prescribed.

² Clinical Knowledge Summaries (CKS) are concise, accessible summaries of current evidence for primary care professionals. CKS topics are developed by Clarity Informatics Ltd but commissioned and funded by NICE. The development process is accredited by NICE. However, NICE CKS does not constitute formal NICE guidance.

³ The All Wales Medicines Strategy Group (AWMSG) was set up in 2002 to advise Welsh Government on the use, management and prescribing of medicines in Wales.

What is the baseline position?

- When this review was undertaken, none of the Kent and Medway formularies included specific recommendations on melatonin for jet lag
- According to ePACT primary care prescribing data, the former Kent and Medway CCGs spent £530,700 on melatonin (all presentations) for adults (>18 years) in 2019/20. It is unclear what proportion of this prescribing can be attributed to jet lag because it is not possible to analyse ePACT prescribing data according to indication.

Change sheet

Reason for review:

When this review was undertaken, none of the Kent and Medway formularies included specific recommendations on melatonin for jet lag.

Change from baseline:

Currently there is no Kent and Medway wide policy on melatonin for jet lag.

Rationale for PR2021-01:

PR2021-01 is consistent with:

- The National Health Service (General Medical Services Contracts) Regulations 2015, which states that GPs are not required to prescribe medicines for the treatment of a condition that is not present and may arise while a patient is abroad
- The AWMSG, which does not endorse the use of melatonin 1mg/ml oral solution or 3mg tablets (both Colonis Pharma Ltd) within NHS Wales for the short-term treatment of jet lag in adults (2019)
- NICE CKS on jet lag (2019), which states that melatonin should not be recommended to promote sleep in jet lag.

Estimated cost impact of implementing PR2021-01:

It is not possible to estimate the cost impact of implementing PR2021-01, because it is not possible to analyse prescribing data according to indication for melatonin treatment. However, implementing PR2021-01 is likely to be cost neutral or lead to a small cost saving.