**Melatonin Prescribing Guideline**

With the exception of short term use (maximum 13 weeks) in the over 55s, melatonin is classed as Amber specialist initiation on the Humber and North Yorkshire Area Prescribing Committee formulary for the indications listed below.

**Humber and North Yorkshire health and care partnership does not routinely support the use of melatonin for indications not listed in this document e.g. sleep disturbances related to shift work, adults who are blind, dementia, chronic fatigue syndrome / myalgic encephalomyelitis / encephalopathy, sleep apnoea, as an adjunct to hypnotic withdrawal and jet lag (unless an approved indication co-exists).**

**Use in cluster headache and melatonin-induced sleep EEG are both classed as Red (secondary care use only).**

**Drug Holidays**

All suitable patients should undergo a two-week drug holiday to assess their need for ongoing treatment. This should take place three months after the commencement of treatment and six monthly thereafter. If sleep improvements are maintained without melatonin, therapy should be stopped[[1]](#footnote-2).

**Transition**

For children and young people who are transitioning into adult services, melatonin prescriptions should be reviewed as per NICE guidance.

[NICE guideline (NG87) Attention deficit hyperactivity disorder: diagnosis and management](https://www.nice.org.uk/guidance/ng87/resources/attention-deficit-hyperactivity-disorder-diagnosis-and-management-pdf-1837699732933) states: "A young person with ADHD receiving treatment and care from CAMHS or paediatric services should be reassessed at school-leaving age to establish the need for continuing treatment into adulthood. If treatment is necessary, arrangements should be made for a smooth transition to adult services with details of the anticipated treatment and services that the young person will require. Precise timing of arrangements may vary locally but should usually be completed by the time the young person is 18 years. See NICE's guideline on transition from children's to adults' services for young people using health or social care services. [2008, amended 2018]"

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| Indication | Formulary Classification | Pre-melatonin prescribing requirements | Monitoring frequency (efficacy) | Duration of treatment |
| Insomnia disorder (for adults aged 55 years and over) | Green with pathway - [Managing insomnia](https://cks.nice.org.uk/topics/insomnia/management/managing-insomnia/)  (after sleep hygiene measures have been tried and following Cognitive Behavioural Therapy (CBT) or a trial of a sleep app e.g. Sleepio (NICE MTG70, May 2022) where available | Basic sleep hygiene | A review is suggested after 1- 2 weeks to ensure a total of 13 weeks will be needed | Maximum of 13 weeks |
| Sleep disorders and Attention Hyperactivity Disorder (ADHD) – children aged 6 to 17 years | Amber specialist initiation | Sleep hygiene measures | Efficacy should be assessed after at least 3 months of treatment (prior to transfer to primary care) and every 6 months thereafter | As advised by specialist. During treatment, especially if the treatment effect is uncertain, discontinuation attempts should be made regularly e.g. at least annually. Should be discontinued prior to transfer to adult services |
| Autism Spectrum Disorder – children aged 2 to 18 years | Amber Specialist Initiation | Sleep hygiene measures | Efficacy should be assessed after at least 3 months of treatment (prior to transfer to primary care) and regularly thereafter | As advised by specialist. During treatment, regularly review ongoing need for a pharmacological intervention and ensure benefits continue to outweigh risks. Should be discontinued prior to transfer to adult services |
| Cerebral Palsy – under 25 years of age  (Off-label use) | Amber Specialist Initiation | Exclude treatable causes for sleep disturbance, sleep hygiene measures | Efficacy should be assessed after at least 3 months (prior to transfer to primary care) | As advised by specialist. |
| Sleep conditions in those with Challenging behaviour and learning disabilities  (Off-label use) | Amber Specialist Initiation | Sleep hygiene measures and behavioural interventions | Efficacy should be assessed after at least 3 months (prior to transfer to primary care) | As advised by specialist. During treatment, regularly review ongoing need for a pharmacological intervention and ensure benefits continue to outweigh risks |
| Refractory rapid eye moving (REM) sleep behaviour disorder in adults with Parkinson's Disease / Lewy Body Dementia  (Off-label use) | Amber Specialist Initiation | Exclude possible pharmacological causes, sleep hygiene measures | Efficacy should be assessed after at least 3 months (prior to transfer to primary care) | As advised by specialist. |

**Product Choice**

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| Melatonin 2mg MR tablets- prescribe generically (Adults) | Primary Insomnia (over 55s) |
| Melatonin 2mg MR tablets (prescribe generically) (Children and Young People) | For continuation of established prescribing (NOT for new patients) |
| Adaflex (immediate release tablets 1mg, 2mg, 3mg, 4mg, 5mg) - Children and Young People | FIRST CHOICE option unless child has autism spectrum disorder (ASD) and /or neurogenetic disorders with aberrant diurnal melatonin secretion and /or nocturnal awakenings (Slentyo is licensed for these children) and sleep hygiene measures have been insufficient. |
| 1-5mg tablets (Adaflex®) can be crushed and mixed with water directly before administration as a licensed use for insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient. This is more cost – effective than prescribing the oral solution. |
| Slenyto MR tablets (1mg, 5mg) - Children and Young People | Licensed for the treatment of insomnia in those aged 2-18 with Autism Spectrum Disorder (ASD) and / or neurogenetic disorders with aberrant diurnal melatonin secretion and /or nocturnal awakenings where sleep hygiene measures have been insufficient. |
| Melatonin oral solution 1mg / ml | Restricted to those who cannot take crushed Adaflex e.g. those with feeding tube.  Specify brand on prescription  **Children under 6 years of age** (NB – unlicensed use): [**Melatonin Consilient Health**](https://www.consilienthealth.co.uk/products/)1 mg/ml oral solution  **Children over 6 years of age:** [**Ceyesto**](https://www.medicines.org.uk/emc/product/15067/smpc)1mg/ml Oral Solution |
| Melatonin 2mg MR tablets (prescribe generically) | For other unlicensed indications |
| Melatonin (Hospital Use Only) - Adaflex | Approved for use by Neurophysiology for sedation in children and adults undergoing sleep EEG. |
| Melatonin capsules (Colonis) | DO NOT PRESCRIBE (licensed for short term treatment of jet lag in adults and capsules are high cost) |

1. [PrescQIPP bulletin - Melatonin](https://www.prescqipp.info/media/zyobihaq/318-melatonin-2-0.pdf) [↑](#footnote-ref-2)