



Management of Insomnia Guidelines in Adults

Management of Insomnia Guidelines in Adults

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Version Control

Guideline Title	Management of Insomnia Guidelines in Adults
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Key changes to policy document

Version	Date	Summary of key changes
1	November 2024	New NLFT document
1.1	September 2025	Minor update: 8.3.7. sentence changed from: 'since daridorexant takes an average of 5-6 weeks to show benefit' to 'since daridorexant takes an average of 5-6 weeks to show full benefit' <u>Appendix: Prescribing information: Warning and Precautions – removal of statement following updated Summary Product of Characteristics (SPC): Daridorexant should be used with caution in patients with severe obstructive sleep apnoea (OSA)</u> <u>7.5</u> Haringey added to the list of talking therapy services providing CBT for insomnia
1.2	December 2025	Minor update: 'For Adults' added to title and in main document - Spelling/formatting corrections, and removal of Appendix A: 'Algorithm for the assessment and management of short -term insomnia' as this had already been superseded by the NCL Insomnia Pathway (which is now Appendix A rather than Appendix B)

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Equality Statement

All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on equality and fairness.

All Trust policy documents will be equality impact assessed and this will include equality and human rights with regard to the protected characteristics including age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) and sexual orientation.

The Trust will make accessible versions of this document available where requested by members of the public, service users or staff.

Trust Vision and Values

We are guided in all we do by our **vision** and **values** and all Trust policies and procedures are written in line with them.

Our **vision** is better mental health, better lives, better communities.

Our **values**:



1. Trust Guidance on a Page: Management of Insomnia Guidelines

What does the guidance cover?

- The definition of insomnia
- The use of non-pharmacological interventions including sleep hygiene and CBT -I
- General prescribing advice for the use of sleeping medications
- Advice on withdrawal process

Summary of what has changed since the last version?

- This is a new NLFT guideline.

To whom does the guidance apply?

- All clinical in-patient and community staff who work with adults

Who can I contact?

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What training is available?

Junior doctors' induction programme which signposts key prescribing and

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2. INTRODUCTION

- 2.1 Insomnia is the most common sleep-wake disorder and can be defined as the persistent difficulty with sleep onset, sleep maintenance or early waking, or quality of sleep, which occurs despite adequate opportunity and circumstances for sleep.
- 2.2 Insomnia is categorised according to its duration or likely duration:
- **Short-term insomnia** is characterised by symptoms occurring for less than 3 months (typically a few days or weeks)
 - **Chronic insomnia** is characterised by insomnia occurring:
 - on at least 3 nights per week
 - for 3 months or more
 - and associated with impairment to day-time functioning or well-being.
- 2.3 The historical perspective that insomnia could be either 'primary' or 'secondary', is no longer regarded as valid or evidence based (ref: BAP 2019). Rather, insomnia often has a bidirectional relationship with other mental and physical health conditions, and insomnia can pre-date other mental illness.

3. PURPOSE

- 3.1 To provide clear guidance on the management of insomnia in adults, including the appropriate and safe use of medication.

4. SCOPE

- 4.1 The guidelines cover the non-pharmacological and pharmacological management of insomnia in adults. It includes the use of sleeping medications including benzodiazepine hypnotics, z-hypnotics, melatonin, sedating antihistamine, sedating antidepressants/antipsychotics (when chosen for their dual effects of treating insomnia and a comorbid mental health problem), and the new medication daridorexant for the treatment of insomnia.
- 4.2 It applies to all clinical staff working in the Trust who work with adults.

5. HOW INSOMNIA DEVELOPS

- 5.1 Developing chronic insomnia is influenced by predisposing, precipitating and perpetuating factors. Short-term insomnia often develops due to a trigger/precipitator, such as a short-term physical illness or stress. The insomnia should resolve once the trigger has ended. However, perpetuating factors, such as people's behaviours and cognitions around sleep, may lead to the short-term insomnia becoming a chronic insomnia disorder. This is shown in the **Figure 1**. However, by giving advice about these perpetuating behaviours and cognitions, this may prevent a short-term insomnia from becoming chronic (this will be covered in the section 7 'Non-pharmacological treatment'). Precipitating and perpetuating factors should be established in the assessment (see Tables 1 and 2 in the Assessment section below).

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Figure 1:

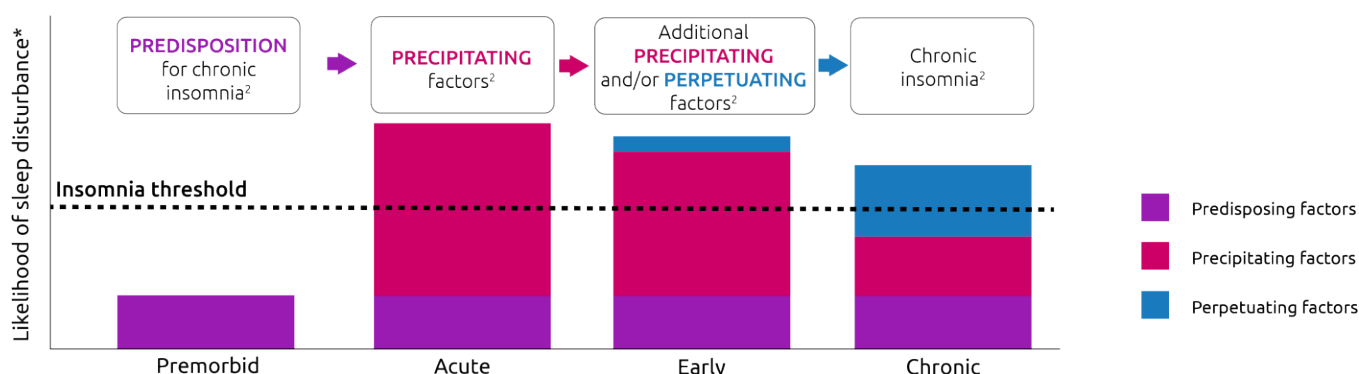


Figure adapted from Spielman AJ, et al. Psychiatr Clin North Am. 1987;10:541–553; 2. Drake CL, Roth T. Sleep Med Clin. 2006;1:333–349

6. ASSESSMENT

6.1. History taking should include enquiry about:

- **Duration and frequency** of sleep difficulty.
- **Sleep patterns:** 'Take me through a typical 24 hours' – time to bed, time taken to get to sleep, night-time awakenings, final time they wake up, time they get up, plus any daytime napping.
- **Daytime impact** (e.g., impact on mood, energy, concentration, quality of life, relationships, social life, employment).
- Any **precipitating factors** (see Table 1 below), including sleep environment (e.g., noise, light, children/pets disturbing sleep, temperature, electronic devices, sharing a room) and any medications or substances used. If precipitating factors are identified, these should be treated where possible. Note that insomnia may also have a bidirectional relationship with many of these factors.
- Any **perpetuating factors** (see Table 2). Enquire about cognitions (e.g., excessive worry about their sleep and anxiety at night) and behaviours (e.g. what they do in between going to bed and falling sleep or if they awaken in the night, are they lying in bed tossing and turning, are they oversleeping or napping to compensate?).
- Symptoms suggestive of another sleep disorder (see Table 3 below). If one is potentially identified, refer the patient to an appropriate sleep clinic.

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Table 1: Factors Precipitating Insomnia		
Precipitating Factors	Examples (not an exhaustive list)	Example management
Physical health problems	• Acute or chronic pain. • Cardiovascular – e.g., angina or congestive heart failure. • Respiratory disease – e.g., COPD, asthma. • Neurological – e.g., Alzheimer's disease, Parkinson's disease. • Endocrine – e.g., thyroid dysfunction. • Other acute or chronic physical illnesses	• Optimise treatment of physical health
Physiological and Environmental	• External stimuli, e.g., a snoring partner, lack of privacy, 'bed poverty'. • Too much light or poor room temperature control. • Late-night heavy meals or exercise.	• Optimise sleeping environment where possible
Stress/ Psychological	• Situational stress e.g., occupational, interpersonal, financial, housing, academic, medical, and environmental stress. • Emotional factors e.g., tension, grief, anger	• Waiting for situation to resolve, debt support, housing support, counselling or therapy
Psychiatric	• Comorbid mental illness e.g., anxiety disorders, depression, bipolar affective disorder, obsessive-compulsive disorder, post-traumatic stress disorder, psychotic disorders	• Treatment of comorbid mental illness may improve insomnia, and treatment of insomnia may improve comorbid mental illness
Pharmacological	• Antihypertensives e.g., betablockers, calcium channel blockers • Some antipsychotics – e.g., aripiprazole, and sedating antipsychotics may lead to napping or oversleeping in the morning which impacts sleep at night. • Some antidepressants – e.g., serotonin reuptake inhibitors, venlafaxine, bupropion, duloxetine, monoamine oxidase inhibitors. • Antiepileptics e.g., lamotrigine, phenytoin. • Stimulants e.g., ADHD medication, modafanil • Sympathomimetics - salbutamol, salmeterol, theophylline, pseudoephedrine. • Dopamine agonists e.g., Parkinson's medications • Diuretics • Corticosteroids • Thyroid hormones	• Consider reducing, stopping or switching offending medications, if indicated • Consider switching offending medications to the morning. • Consider switching medication to a more sedating alternative medication at night
Substance use	• Alcohol • Recreational drugs including cannabis • Nicotine • Caffeine	• Reducing or stopping the substance • Reducing evening use of the substance • Reducing/avoiding caffeine after 1pm

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Table 2: Factors Perpetuating Insomnia

Perpetuating Factors	Examples	Example interventions
Cognitive	Excessive worry about sleep, getting to sleep and staying asleep, such that it increases anxiety and stops them from sleeping	Cognitive behaviour therapy for insomnia (CBT-I) (see Section 7: Non-pharmacological treatment)
Behavioural	Compensating for lack of sleep by going to bed too early, oversleeping in the morning, and/or napping	- Introduce techniques from CBT-I: e.g. advise to get up at the same time every day, not to go to bed until they are sleepy and it is past a reasonable hour (set an 'earliest bedtime'), avoid the bedroom except for sleep/getting dressed, and avoid napping (see Section 7: Non-pharmacological treatment) - Refer for formal CBT-I treatment using stepped care approach (see Section 7)

Table 3: Screening for Other Sleep-Wake Disorders

Examples (not an exhaustive list)	Example screening and management
Sleep apnoea.	- Screening for comorbid sleep disorders (e.g., Via the Epworth Sleepiness scale (a high score indicates a possible sleep disorder such as sleep apnoea or periodic limb movements, as people with only insomnia are not usually excessively sleepy), STOPBANG questionnaire (a high score indicates possible sleep apnoea); refer to respiratory sleep clinic if likely to have sleep apnoea. - Reference STOP-BANG Score for Obstructive Sleep Apnea - Reference: https://www.msdmanuals.com/professional/multimedia/clinical-calculator/epworth-sleepiness-scale-ess
Disruption of circadian rhythm, e.g., from jetlag or shiftwork.	Find out whether the key problem is due to these.
Sleep-wake phase syndrome (circadian sleep disorder)	Find out whether the key problem is due to the timing of sleep (e.g., if society allowed them to sleep from late at night until late morning, would they sleep well?)
Narcolepsy	Ask about falling asleep without much warning
Parasomnias e.g., restless legs syndrome, sleep walking, night terrors.	Ask about nightmares, acting out dreams, or sleepwalking.

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Periodic limb movements	Ask about whether they seem to kick out while asleep (e.g., reported by sleeping partner, bed covers on the floor); screening for comorbid sleep disorders (e.g. Via the Epworth Sleepiness scale (a high score indicates a possible sleep disorder such as sleep apnoea or periodic limb movements, as people with only insomnia are not usually excessively sleepy),
Restless legs syndrome	Do they experience an unpleasant sensation in their legs with the urge to kick out or move? Does this impact their sleep? This can be differentiated from akathisia, as restless legs syndrome is worse at night when they go to bed and is relieved temporarily by kicking/moving, whereas akathisia is not.

7 NON-PHARMACOLOGICAL TREATMENT

- 7.1 Cognitive-behaviour therapy for insomnia (CBT-I) is the first-line treatment for chronic insomnia, recommended by NICE. Its techniques are also useful for preventing acute insomnia from becoming chronic, by targeting the perpetuating factors (cognitive and behavioural factors shown in Table 2, Section 6). It is the only treatment for insomnia that provides a permanent cure and once learnt, its techniques can be used to prevent a new bout of acute insomnia from becoming chronic again in the future.
- 7.2. A large body of high-quality research has shown that CBT-I is 70-90% effective at treating insomnia and is effective regardless of comorbid physical or mental health conditions that the person has (trials have included patients with chronic pain, cancer, COPD, bipolar affective disorder, depression, anxiety, PTSD, and many other conditions). CBT-I reduces the chance of other mental disorders developing, reduces the severity of many comorbid disorders (including depression and anxiety), allows better response to treatment for comorbid disorders, and helps prevent relapse of comorbid disorders.
- 7.3. CBT-I is rarely unsuitable. It is only unsuitable if the person is unwilling or unable to engage in a 1:1 or group therapy (e.g., due to severe mental illness impacting cognition, active psychotic symptoms, mental health crisis, or substance misuse if this would impact their ability to engage).
- 7.4. The person's clinician (e.g., GP, nurse or psychiatrist) should provide psychoeducation and explanation of key CBT-I techniques. Key techniques that can easily be explained during a routine consultation include:
- Getting up at the same time every day, 7 days per week, regardless of how well they slept.
 - Avoiding napping in the daytime
 - Learning progressive muscular relaxation
 - Practicing sleep stimulus control (avoiding the bed and ideally also the bedroom when it is not time to sleep, and only using the bedroom for sleep, intimacy and getting dressed; leaving the bedroom if they have not been able to sleep for around 15-20 minutes and only returning to bed when sleepy)
 - Sleep restriction and sleep compression involve reducing the window in which the person is permitted to sleep. Once a morning wake-up time has been set, an 'earliest bedtime' can be set a few hours before, and the person should only go to sleep when it is both past their earliest bedtime and they are feeling sleepy. Sleep restriction should only be practiced by clinicians who have learnt how to do this and which diagnoses (e.g., bipolar affective disorder and epilepsy) would require a more cautious approach. For clinicians not familiar with this, a safe approach would be to set an earliest bedtime no more than 8 hours before the

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rising time. This means that someone who is getting up at 7am, for example, should not be going to bed before 11pm at the earliest.

- 7.5. The decision of where to then refer the person for CBT-I would be impacted by various factors. CBT-I should be done as part of a stepped care process, depending on what has already been tried, insomnia severity, complexity of the person's mental health problems, and other comorbid conditions. This is summarised below and in the insomnia pathway flowchart in Appendix A:
- Step 1: CBT-I apps e.g. Sleepful is currently free to use; Sleepio is recommended by NICE but not yet commissioned at the time of writing these guidelines
 - Step 2: Referral to the local talking therapies service if available (at the time of writing this, Camden, Islington and Haringey talking therapies were providing CBT-I, but not Barnet or Enfield) and if suitable without severe or complex mental health comorbidity, epilepsy (see Appendix A)
 - Step 3: Referral to an insomnia sleep clinic (e.g., UCLH, or Guy's Hospital if there is a comorbid sleep disorder).
- 7.6. CBT-I includes psychoeducation (including on sleep hygiene and on the rationale for the cognitive-behavioural techniques), 'sleep stimulus control', sleep restriction therapy/sleep compression therapy, relaxation techniques, and various cognitive strategies.
- 7.7. Sleep hygiene is not usually effective as a standalone treatment for chronic insomnia, as it is the other aspects of CBT-I that have the greater evidence base. However, it should be included alongside the other techniques within the broader context of CBT-I. Additionally, sleep hygiene may be useful in acute insomnia or for those who would be unable to engage in CBT-I. The person should be advised on the following in Table 4:

Table 4: Sleep Hygiene	Comment
Sleep environment	• Maintenance of a comfortable sleeping environment: not too hot, cold, noisy, or bright. • The bedroom should only be used for sleep and intimacy. • Avoid checking or watching the clock throughout the night. • Minimise bright light including all technology (i.e.: blue light filter, social media timer limits, etc). 'Blue light' displays on electronic devices and televisions suppress melatonin production — avoid using devices for at least an hour before bed.
Regular sleep schedules	• Going to bed when sleepy — avoid going to bed too early. • Waking up and getting out of bed at the same time every morning including weekends and after a poor night's sleep — increase exposure to bright light in the morning. • Avoid napping during the day. • Relaxation before going to bed (for example reading a book, having a bath, or listening to music).
Limiting/avoidance of caffeine, nicotine, and alcohol.	• Avoid caffeine after midday and nicotine, alcohol, and large meals within 2 hours of bedtime. Consider complete elimination of caffeine from the diet. • Alcohol intake may cause sedation but is a common maladaptive self-treatment strategy for insomnia, which can contribute to poor sleep-maintenance. • Avoid eating a heavy meal late at night.

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Exercise	Avoid vigorous exercise within an hour of bedtime but is beneficial earlier in the day and overall regular physical exercise can help with relaxation and better sleep.
Information	- Make available a copy of the sleep hygiene leaflet from the Choice and Medication leaflet - handyfactsheetsleephygieneuk.pdf (choiceandmedication.org) Other information sources include: How to fall asleep faster and sleep better from NHS Every Mind Matters. Simple tips for better sleep from NHS Every Mind Matters. How to sleep better from the Mental Health Foundation. - NHS Insomnia https://www.nhs.uk/conditions/insomnia/ - RCPsych Sleeping Well https://www.rcpsych.ac.uk/mental-health/mental-illnesses-and-mental-health-problems/sleeping-well

8 PHARMACOLOGICAL TREATMENTS

8.1 General

- 8.1.1. Z-drugs and benzodiazepines as hypnotics should be reserved for short courses (3-7 days) in the acutely distressed, where sleep hygiene has failed, and insomnia is likely to resolve soon.
- 8.1.2. Tolerance to the effects of benzodiazepines and z-hypnotics develops within 3-14 days of continuous use and long-term efficacy cannot be assured.
- 8.1.3. Withdrawal after long-term use can cause rebound insomnia and a withdrawal syndrome. Note that this is not the case with daridorexant (reference emc).
- 8.1.4. Where possible, concurrent sedative medicines should be prescribed at night and medicines likely to disturb sleep should be prescribed during the day.
- 8.1.5. Service users must be advised not to drive or operate machinery after taking their hypnotic/ sleep medication, until they know how it affects them (especially just after starting or changing the dose). It is against the law to drive if the ability to do so is impaired by medicine.
- 8.1.6. The lowest effective dose should be used.
- 8.1.7. Benzodiazepine and z-hypnotics should usually be prescribed as a short course only (e.g. 3-7 days) .Do not prescribe hypnotics routinely unless it has clearly been established and documented that hypnotics are of ongoing benefit to the service user.
- 8.1.8. Use of intermittent dosing (e.g. alternate nights) is not advised, as this can lead to increased psychological dependence and distress.).
- 8.1.9. Advice should be given on the interaction with alcohol and other sedating medicines.
- 8.1.10. Do not prescribe z-drugs or benzodiazepines to older people (unless essential) or women who are pregnant or breastfeeding.

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8.2 Short-term insomnia (< 3 months)

- 8.2.1 First, ensure a thorough assessment including consideration of any modifiable precipitating and perpetuating factors (see Section 6) and consider non-pharmacological treatment options (see Section 7).
- 8.2.2 If sleep hygiene measures fail, daytime impairment is severe causing significant distress, and insomnia is likely to resolve soon (for example due to a short-term stressor) consider a short course of a non-benzodiazepine hypnotic medication (z-drug).
- 8.2.3 Use the lowest effective dose for the shortest period possible. The exact duration would depend on the underlying cause, but treatment should not be continued for longer than two weeks
- 8.2.4 Advise the person that further prescriptions for hypnotics will not usually be given, ensure the reasons for this is understood and document in the person's clinical notes. Do not issue further prescriptions without seeing the person again.
- 8.2.5 If there is no response to the first hypnotic, then another one should not be prescribed (as per NICE guidance).
- 8.2.6 If the person experiences adverse effects considered to be directly related to the hypnotic, consider switching to another.
- 8.2.7 Review after two weeks and consider referral for cognitive behavioural therapy (CBT-I) if symptoms persist.
- 8.2.8 Do not recommend over-the-counter treatments for insomnia.

8.3 Chronic insomnia (>3 months)

- 8.3.1 First, ensure a thorough assessment including consideration of any modifiable precipitating and perpetuating factors (see Section 6).
- 8.3.2 CBT for insomnia (CBT-I) is the first-line treatment for chronic insomnia recommended by NICE and is highly effective. Therefore, a stepped care approach should be taken to refer patients for CBT-I, except in rare situations where CBT-I would be unsuitable (see Section 7).
- 8.3.3 Pharmacological treatment for chronic insomnia would only be suitable if the patient is unsuitable for CBT-I or has already tried CBT-I, or in situations where a patient requires insomnia treatment while on the waiting list for CBT-I (this would depend on factors such as the waiting list for CBT-I and the how much the insomnia is impacting the patient's life, and should be a shared decision between the clinician and the patient). See the decision tree in **Appendix A** for further information on referral processes and medication decisions.
- 8.3.4 The first-line pharmacological treatment for chronic insomnia is daridorexant, as recommended by NICE (second - line after CBT-I). See below for further prescribing information on daridorexant.
- 8.3.5 Long-term treatment with z-drugs or benzodiazepines should only be considered in rare situations where both CBT-I and daridorexant are either unsuitable, ineffective or not tolerated, and where the patient's insomnia would otherwise cause a significant

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negative impact to their health and quality of life. For information on withdrawal of hypnotic medication, see the CKS topic on Benzodiazepine and z-drug withdrawal. (<https://cks.nice.org.uk/topics/benzodiazepine-z-drug-withdrawal/>)

- 8.3.6 For people over 55 years of age with persistent insomnia, treatment with a prolonged-release melatonin may be considered.
- 8.3.7 Pharmacological treatment should be reviewed after a reasonable period of time (around 3 months after starting daridorexant, since daridorexant takes an average of 5-6 weeks to show full benefit). Treatment should be stopped in people whose chronic insomnia has not responded adequately. Suitability for CBT-I should also be reviewed at that time, and the person should be referred for CBT-I if they become suitable for it. If medication is continued, assess again at regular intervals whether it is still working and whether the person has become suitable for CBT-I.

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8.4 FORMULARY

8.4.1 Here is a list of Trust formulary options:

Table 5: Summary of pharmacological choice for the management of insomnia (further details are in the sections below this table)				
Medicine choice formulary	NCL JFC Approval	CD schedule	Relative Cost	Comments
Zopiclone/ Zolpidem	Short-term insomnia	4	+	- NICE TA 77 Do not prescribe to older people (unless essential) or women who are pregnant or breastfeeding. Zolpidem has the shorter half-life (around 4-6 hours), compared with zopiclone (around 6-8 hours), and should be considered for those who have not used a z-hypnotics before or where sleep onset is an issue rather than sleep duration. Zopiclone should be considered for those where a longer duration of action is required, such as where sleep maintenance is an issue. - Zopiclone dose 3.75 - 7.5 mg at bedtime; Zolpidem dose: 5-10mg at bedtime. - Zolpidem should not be used in those with psychosis. Zopiclone should be used cautiously in those with psychotic symptoms. - The lowest effective dose should be used.
Daridorexant	Chronic insomnia	N/A	++	- Approved as the first-line medication treatment for the management of chronic insomnia (second-line after CBT-I) as per the criteria stated in the NCL Insomnia Pathway (see Appendix A). (NICE TA922) Daridorexant for treating long-term insomnia (October 2023) - It is not considered a 'hypnotic' as it works on different brain pathways to hypnotics. - Dose: (Adult) 50 mg once per night, 30 minutes before going to bed. Some patients may be treated with 25 mg at night, however, unless contraindicated, the usual dose is 50mg per night since research showed that dose to be significantly more effective than 25mg. Further information on daridorexant is below, including which groups may need dose adjustment. - No dose adjustment is required in older adults.
Temazepam	Short-term insomnia	3	++++	10-20 mg at bedtime, exceptionally dose may be increased to 30-40 mg at bedtime
Melatonin	Insomnia (short- and long-term in adults aged ≥55 years)	N/A	+	Approved as second line treatment for up to 13 weeks, after zopiclone, zolpidem, or a benzodiazepine.
Melatonin	Additional indications	N/A	+	See NCL Fact sheet https://nclhealthandcare.org.uk/fs_melatonin/?UNLID=8079023352025213151956

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Promethazine	Pregnant women only	N/A	++	• Approved for hypnotic for pregnant women (off-label). Should NOT be used as a sleeping tablet except for pregnant women. • NICE CG 192. Antenatal and postnatal mental health: clinical management and service guidance (December 2014)
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8.5 Z-Hypnotics

8.5.1 Z-hypnotics are recommended by NICE for the short-term management of severe insomnia that interferes with normal daily life and should be prescribed short term.

8.5.2 Zolpidem should be considered the first-choice z- hypnotic for service users who have never used a z-hypnotic and in those where there are issues with sleep onset and where daytime effects need to be at a minimum. It has a shorter half-life (around 4-6 hours) compared with zopiclone (around 6-8 hours). Note it is contraindicated in patients with psychotic illness.

8.5.3 Zopiclone should be considered where sleep maintenance is an issue, and a longer duration of sleep is needed. Zopiclone does not have a contra-indication for psychosis as part of its marketing authorisation, however psychiatric reactions have been reported with its use (see SPC), like, delusion, hallucinations, abnormal behaviour.

8.5.4 The lowest effective dose should be used.

Promethazine

8.6

8.6.1 Do not prescribe promethazine for insomnia, except for pregnant women if non-pharmacological interventions are unsuccessful (see section 9.5). It is not recommended by national guidelines and carries a high anticholinergic burden, which carries short-term side-effects (such as dizziness and blurred vision) and long-term risks (including to memory and cognition). It can also be dangerous in overdose.

8.7. Melatonin

8.7.1. Melatonin is available for:

- Adults aged ≥ 55 years, second line for up to 13 weeks, after zopiclone, zolpidem, or a benzodiazepine, in line with melatonin factsheet
- Autism spectrum disorders or Smith-Magenis syndrome.
- Insomnia in children, adolescents, adults with learning disabilities (off label use)
- Insomnia for children (>2 years) and adolescents with neurological or developmental disorders.
- Circadian rhythm disorders
- REM sleep behaviour disorders, including in patients with Parkinson's disease.
- Sleep disorders caused by visual impairment.

8.7.2 In children, young people and adults with a learning disability and challenging behaviour, melatonin should only be offered after behavioural interventions for sleep problems have not improved sleep issues.

8.7.3 Higher doses, up to a maximum of 12mg daily, may be required for people with learning disabilities.

8.7.4 Treatment should be reviewed regularly, at 3-6 monthly intervals. For patients without learning disabilities, melatonin will be unlicensed and should only be initiated via sleep clinic.

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- 8.7.5 See NCL Melatonin factsheet. https://nclhealthandcare.org.uk/wp-content/uploads/2024/07/FS_Melatonin.pdf

8.8 Daridorexant

- 8.8.1 Daridorexant is recommended for treating chronic insomnia in adults (i.e., those with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is affected), if CBT-I has been tried but not worked, or CBT-I is not available or is unsuitable. 'Unavailable' could include CBT-I not being immediately available (i.e., the patient is on a waiting list for CBT-I and requires a sleeping tablet in the meantime). See Section 8.3. (Pharmacological Treatment of Chronic Insomnia) and Appendix A (NCL Insomnia Pathway) for further details on when to prescribe.
- 8.8.2 The length of treatment should be as short as possible. Treatment with daridorexant should be assessed within 3 months of starting and should be stopped in people whose long-term insomnia has not responded adequately. If treatment is continued, assess whether it is still working at regular intervals.
- 8.8.3 Within the Trust, it is approved as a first line sedative for the management of chronic insomnia as per the criteria stated in the NCL Insomnia Pathway.
- 8.8.4 See Daridorexant for treating long-term insomnia TA 922 (October 2023) <https://www.nice.org.uk/guidance/ta922?UNLID=3015295852024121832351>

8.9. Medicines not approved for the treatment of insomnia (as a main indication)

- 8.9.1 The following interventions should not be used as the sole treatment of insomnia because of poor evidence base and / or increased adverse effects:

Table 6: Interventions not approved for the treatment of insomnia	
Intervention	Comment
Antidepressants	Longer-lasting residual effects than traditional hypnotics. Consider the toxicity of tricyclic antidepressants in overdose; SSRIs generally disrupt sleep early in course of treatment; SSRIs, venlafaxine, mirtazapine increase the risk of restless legs syndrome and periodic limb movements in sleep.
Antihistamines (including promethazine)	Long duration of action and can often cause drowsiness the following day. The sedative effect of antihistamines diminishes after a few days of continued treatment.. NB: promethazine is included in the formulary for pregnant women (off-label) and acute phase of mania and aggression/rapid tranquillisation (off-label) (2nd line option)..
Antipsychotics -	Evidence weak and potential side effects outweigh expected benefits. Also a few case reports of abuse of quetiapine* in inpatients and in prisons.
Diazepam	Long half-life, which commonly gives rise to next-day residual effects and repeated doses tend to be cumulative.
Chloral hydrate, clomethiazole, barbiturates	Toxic in overdose; and there is insufficient evidence to support their use.

*Ref: [Quetiapine Misuse and Abuse: Is it an Atypical Paradigm of Drug Seeking Behavior? - PMC](#)

9 CAUTIONS and CONTRA-INDICATIONS

9.1 For information on individual hypnotics, see the individual summary of product characteristics (SPC) (<https://products.mhra.gov.uk/> or <https://www.medicines.org.uk/emc/#gref>) or contact the Pharmacy department for advice.

9.2 Avoid the use of hypnotics in patients with respiratory disease or severe hepatic impairment and addiction-prone individuals⁴. Use benzodiazepines and z-hypnotics cautiously in older adults.

9.3 Hepatic impairment:

9.3.1 **Zopiclone** – can precipitate coma and respiratory depression. Reduce the dose. Avoid in severe impairment.

9.3.2 **Zolpidem** – can precipitate coma and respiratory depression. Reduce the dose to 5mg. Avoid in severe impairment.

9.3.3 **Benzodiazepines** - can precipitate coma and respiratory depression if used in hepatic impairment. If treatment is necessary, temazepam has a shorter half-life compared to other benzodiazepines. Smaller doses should be initiated and avoid in severe impairment². Temazepam may precipitate encephalopathy in severe hepatic impairment.

9.3.4 **Daridorexant** - In mild hepatic impairment, no dose adjustment is required. In moderate hepatic impairment, the recommended dose is 25 mg per night. In patients with severe hepatic impairment, daridorexant is not recommended.

9.3.5 **Melatonin** -- is not recommended for use in patients with hepatic impairment.

9.3.6 **Promethazine** - should be avoided in patients with liver dysfunction.

9.4 Renal impairment:

9.4.1 **Zopiclone** –accumulation has not been noted during treatment of insomnia, but a lower starting dose of 3.75mg is recommended by the manufacturer.

9.4.2 **Zolpidem** – use with caution, due to a moderate reduction in clearance.

9.4.3 **Benzodiazepines** - patients with renal impairment have increased cerebral sensitivity to benzodiazepines. Smaller doses should be started in severe impairment. Temazepam may precipitate encephalopathy in severe insufficiency.

9.4.3 **Daridorexant** - in patients with renal impairment (including severe), no dose adjustment is required.

9.4.4 **Melatonin** - caution should be used when melatonin is administered to patients with renal impairment.

9.5 Pregnancy and Breastfeeding

9.5.1 General

9.5.1.1 Non-pharmacological measures are preferred.

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- 9.5.1.2 For those with serious and chronic insomnia, promethazine may be considered.
- 9.5.1.3 Safe sleeping practice should be encouraged - bed sharing is not advised when taking any sedative medication. The following resources may be useful for service users:
- Safer sleep image guidelines - The Lullaby Trust
<https://www.lullabytrust.org.uk/new-partnership-will-save-lives-by-supporting-parents-and-health-professionals-to-reduce-the-risk-of-sids/>
 - Reduce the risk of sudden infant death syndrome (SIDS) - NHS (www.nhs.uk)
- 9.5.1.4 Particular care should be taken for mothers using alcohol or illicit substances.

9.5.2 Z-hypnotics

9.5.2.1 Zopiclone

- **Pregnancy:-** Avoid regular use (risk of neonatal withdrawal symptoms). High doses during late pregnancy or labour may cause neonatal hypothermia, hypotonia and respiratory depression.
- **Breastfeeding:** Zopiclone can be present in breast milk in small amounts so use should be minimised to the lowest dose for the shortest period.

9.5.2.2 Zolpidem

- **Pregnancy:** Avoid regular use (risk of neonatal withdrawal symptoms). High doses during late pregnancy or labour may cause neonatal hypothermia, hypotonia and respiratory depression.
- **Breastfeeding:** Zolpidem can be present in small amounts in breast milk so use should be minimised to the lowest dose for the shortest period..

9.5.3 Benzodiazepines

- **Pregnancy:** First trimester exposure has been associated with increased risk of oral clefts in newborns. In late pregnancy, there is a risk of neonatal withdrawal symptoms; and high doses administered during late pregnancy and labour may cause neonatal hypothermia, hypotonia and respiratory depression. Long acting benzodiazepines accumulate in foetal tissue. They have also been associated with pylorostenosis and alimentary tract atresia. Where benefit of treating outweighs risk, shorter acting benzodiazepines such as lorazepam should be selected at the lowest effective dose for short intervals.

Breastfeeding:

- Benzodiazepines are present in breast milk and should be avoided if possible. Where benefit outweighs risk, shorter acting benzodiazepines such as lorazepam should be selected at the lowest effective dose for short intervals.

9.5.4 Melatonin –

- **Pregnancy:** No clinical data is available.
- **Breastfeeding:** There is limited clinical data, but melatonin is thought to be compatible with breastfeeding'

9.5.5 Daridorexant -

- **Pregnancy:** Avoid use unless essential — no data available.

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- **Breastfeeding:** Avoid use in breastfeeding women if possible, and if not possible, the infant should be monitored for sedation.

9.5.6 Promethazine

- **Pregnancy:** For patients with serious and chronic problems, promethazine may be considered.
- Safe sleeping practice should be encouraged, especially for those taking sedative medications such as those for insomnia. The use of promethazine is not recommended in the 2 weeks prior to delivery in view of the risk of irritability and excitement in the neonate. Particular care should be taken for mother using alcohol or illicit substances.
- **Breastfeeding:** Promethazine is excreted in breast milk. There are risks of neonatal irritability and excitement and therefore it is not recommended for use in breast-feeding.

9.6 Older Adults

- 9.6.1 Standard six of the National Service Framework for older people aims to reduce the number of falls which result in serious injury and ensure effective treatment and rehabilitation for those who have fallen."
- 9.6.2 Benzodiazepines and z-drug hypnotics should be avoided in the elderly because they are at greater risk of becoming ataxic and confused, leading to falls and injury (e.g., hip fractures). If prescribed hypnotics, this group of patients must be closely monitored. A falls assessment must be carried out.
- 9.6.3 No dose adjustment required for daridorexant.

9.7 Benzodiazepines and z-hypnotics (Substance Misuse Services)

- 9.7.1 All new service users, who are assessed as being dependent on benzodiazepines by the Substance Misuse team, will only be prescribed a benzodiazepine detoxification regimen, as there is no evidence to support maintenance prescribing.
- 9.7.2 A detailed description of the service user's pattern of use, withdrawal symptoms, and potential paradoxical symptoms should be identified and documented before commencing prescribing. Particular attention should be given to possible psychiatric morbidity.
- 9.7.3 All prescribing must be considered in relation to the wider substance misuse history, especially concomitant use of alcohol, opiates/opioids and other respiratory depressants.

9.8 Alcohol

- 9.8.1 As benzodiazepines and z-hypnotics can increase the effects of alcohol, patients should be advised not to drink alcohol with these medicines. If a patient appears intoxicated, then administration of the hypnotic should be withheld.
- 9.8.2 Note also that alcohol should not be taken with melatonin, because it reduces the effectiveness of melatonin on sleep; and co-administration of daridorexant with alcohol may lead to additive effects on psychomotor performance.

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10 DISCHARGE FROM HOSPITAL

- 10.1 Hypnotic use should be reviewed prior to discharge. Ordinarily people should not be discharged on hypnotics (every attempt should be made to discontinue these before discharge).
- 10.2 If there is a rationale for on-going prescribing, this must be documented in the person's clinical notes and communicated to the person's GP and secondary care colleagues (or other specialist provider), including proposed treatment plan of when to review, reduce and/or discontinue treatment. In this case no more than 7 days' supply of a hypnotic should be dispensed on discharge unless the prescriber states reasons for extended use.
- 10.3 All changes should be discussed with the person (and carer, if appropriate). If a patient is being discharged on a hypnotic or prescribed a hypnotic in outpatients, a care plan should be forwarded to the GP in relation to discontinuing it.
- 10.2 Where prolonged administration is unavoidable, hypnotics should be discontinued as soon as feasible, and the person warned that sleep may be disturbed for a few days before normal rhythm is re-established. See section 15 (Withdrawal of long-term benzodiazepine / z-hypnotics).
- 10.4 Where patients are discharged on benzodiazepines or Z-hypnotics, a Discharge Medicines Service (DMS) referral should be made by the ward pharmacist to the patient's community pharmacy.
- 10.5 Patients should not be discharged on long-term promethazine to manage agitation, and they should also not be discharged on promethazine for insomnia (unless they are a pregnant woman requiring sleeping medication).

11 DRUG - DRIVING

- 11.1 Service users should be advised about the legal implications if they drive, attempt to drive or are in charge of a vehicle whilst with a specified controlled drug in the body (e.g., temazepam), in excess of a specified limit whether driving is impaired or not. (Section 5A of the Road Traffic Act 1988, amended April 2013).
- 11.2 Also advise them of the statutory medical defence to higher than the specified limits/levels if drug is lawfully prescribed, supplied or purchased over-the-counter, for medical or dental purposes; and if the drug is taken in accordance with advice given by the person who prescribed or supplied the drug, and also in accordance with any accompanying written instructions (so far as the latter are consistent with any advice of the prescriber). Service users should be advised to keep evidence they are taking a benzodiazepine in accordance with medical advice (e.g., medication box with pharmacy label, evidence of repeat prescription).
- 11.3 Prescribers should advise patients of their responsibility to notify the Driver and Vehicle Licensing Agency [DVLA] if they are experiencing effects from the medication they are taking that impairs their ability to drive. Prescribers also should notify the DVLA when a person's fitness to drive requires notification, but the person cannot or will not notify the DVLA themselves.

12 WITHDRAWAL OF LONG-TERM BENZODIAZEPINES AND Z-HYPNOTICS

- 12.1 Long-term prescribing of benzodiazepines /z-hypnotics (especially > 30 mg diazepam equivalent per day) may result in e.g., withdrawal symptoms on discontinuation. Short-acting drugs are associated with more withdrawal issues than the longer-acting ones (e.g., diazepam).
- 12.2 Issues with the withdrawal process can be anticipated if:
- Unsuccessful previous attempts
 - Lack of social support
 - History of alcohol/polydrug abuse
 - Withdrawal seizures
 - Elderly patients
 - Severe psychiatric/physical disorders
 - Personality disorder
 - Withdrawal is too rapid.
- 12.3 Discontinuation symptoms have their peak severity at two days for short half-life and four to seven days for long-half-life benzodiazepines.
- 12.4 Clinicians may be faced with requests to continue a prescription for maintenance benzodiazepines or z-hypnotics. To prevent symptoms of withdrawal, the clinician should continue the prescription, but the dose should be gradually reduced to zero.
- 12.5 The rate of withdrawal will be determined by the individual's capacity to tolerate any withdrawal symptoms. Benzodiazepines can be withdrawn in proportions of between one-tenth and one-quarter of the daily dose every fortnight. When dependence on therapeutic doses occurs, the dose can be reduced initially by 2–2.5 mg and if withdrawal symptoms occur, the dose should be maintained until symptoms improve. If withdrawal symptoms are severe, it may be necessary to increase the dose to alleviate the symptoms.
- 12.6 If necessary, change the benzodiazepine or z-hypnotic to an equivalent nightly dose of the long-acting diazepam. See Table 7 for equivalent doses of benzodiazepines and z- hypnotics.
- 12.7 If very high dose prescribing is required the patient should be referred for specialist assessment. If the patient is stable and free of withdrawal symptoms, at for example 50 mg a day, the dose should be gradually reduced at a faster rate than suggested, for example by half over six weeks and then the planned rate of reduction should be again reviewed in line with the guidance outlined previously. In the inpatient setting it is appropriate to provide a slow withdrawal regimen over one to four weeks, with diazepam starting at a daily dose of no more than 30 mg, and usually less, given in divided doses. If the service user agrees, benzodiazepines should be withdrawn in line with the following considerations:
- 12.8 **Switching to diazepam** – service users should be offered the equivalent dose of diazepam as it has a long half-life. The approximately equivalent doses are in Table 7.

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12.9 Table 7: Approximate equivalent doses of oral benzodiazepine hypnotics licensed in the UK

Table 7:					
Drug	Ashton Manual	BNF	Maudsley Guidelines	Psychotropic Drug Directory	UK Guidelines
Diazepam	5mg	5mg	5mg	5mg	5mg
Flurazepam	7.5 – 15mg	7.5 – 15mg		7.5 – 15mg	7.5 – 15mg
Nitrazepam	5mg	5mg	5mg	5mg (2.5 – 20mg)	5mg
Temazepam	10mg	10mg	10mg	10mg	10mg
Flurazepam	7.5 – 15mg	7.5 – 15mg		7.5 – 15mg	7.5 – 15mg
Oxazepam	10mg	10mg	10mg	10mg (10 – 20mg)	10 – 15mg
Zopiclone	7.5 mg	7.5 mg			
Zolpidem	10mg	10 mg			

- a. These equivalents are based on clinical experience during switch-over to diazepam at the start of withdrawal programs but may vary between individuals.
- b. Inter-patient variability and differing half-lives mean the figures can never be exact and should be interpreted using clinical and pharmaceutical knowledge.
- c. Diazepam is available in a variety of strengths (2mg, 5mg and 10mg), scored tablets and liquid to facilitate switching.
- d. Diazepam substitution may not be appropriate for patients with hepatic dysfunction.

12.10 Examples of reducing schedules Benzodiazepine or Z-hypnotic (>4 weeks)

12.10.1 **Table 8** shows a suggested taper schedule; some patients may tolerate a more rapid reduction and others may require a slower taper.

Table 8: Suggested schedule for reducing dosage of benzodiazepines
Reduce by 10mg/day every one to two weeks to a daily dose of 50mg
Reduce by 5mg/day every one to two weeks to a daily dose of 30mg
Reduce by 2mg/day every one to two weeks to a daily dose of 20mg
Reduce by 1mg/day every one to two weeks until stopped.

12.10.2 Usually no more than one week's supply should be issued at any one time. Gradual dose reduction accompanied by psychological intervention is more likely to be successful than dose reduction alone.

12.11 How to manage withdrawal of long-term z-hypnotics

12.11.1 **Switching to diazepam:** - Exact substitution is not possible due to differences in potency between benzodiazepines and z-hypnotics differences in half-lives and a person's response to medicines e.g., excessive sedation.. Switching to diazepam should be done gradually. Consider making the first switch in the night-time dose to avoid daytime sedation. Dose withdrawal may be started when conversion to diazepam is complete. For dose equivalents, **see Table 7**.

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Table 9: Switching schedules	
Temazepam 10mg to diazepam 5mg	In week 1 convert temazepam 10mg straight to diazepam 5mg.
Temazepam 20mg to diazepam 10mg	In week 1 convert temazepam 20mg to temazepam 10mg and diazepam 5mg. In week 2 convert the remaining temazepam 10mg to diazepam 5mg giving a total of diazepam 10mg daily.
Nitrazepam (non-formulary) 5mg to diazepam 5mg	In week 1 convert nitrazepam 5mg straight to diazepam 5mg.
Nitrazepam (non-formulary) 10mg to diazepam 10mg	In week 1 convert nitrazepam 10mg to nitrazepam 5mg and diazepam 5mg. In week 2 convert the remaining nitrazepam 5mg to diazepam 5mg giving a total of diazepam 10mg daily.
Zopiclone 7.5mg to diazepam 5mg	In week 1 convert zopiclone 7.5mg straight to diazepam 5mg.
Zopiclone 15mg (> BNF max) to diazepam 5mg	In week 1 convert zopiclone 15mg to zopiclone 7.5mg and diazepam 5mg. In week 2 convert the remaining zopiclone 7.5mg to diazepam 5mg giving a total of diazepam 10mg daily.

- 12.11.2 Dose withdrawal may be started when conversion to diazepam is complete. Withdrawal should be gradual e.g., 5-10% reduction every one to two weeks or one-eighth of the dose fortnightly, with a slower reduction at lower doses and titrated according to the severity of withdrawal symptoms. This may take three to four months to a year or longer. Some people may withdraw in less time.

12.12 Suggested withdrawal schedules for temazepam, nitrazepam and zopiclone without diazepam conversion.

- 12.12.1 Withdrawal should be gradual, e.g., 5-10% dose reduction every one to two weeks or one-eighth of the dose fortnightly, with a slower reduction at lower doses and titrated according to the severity of withdrawal symptoms. This may take three to four months to a year or longer. Some people may withdraw in less time.

Table 10: Tapering schedules	
Temazepam ≤20mg at night	Reduce daily dose by a quarter of a 10 mg tablet (2.5 mg) every 2 weeks. Consider temazepam 10mg/5ml liquid to achieve further reductions if needed. Target dose is 2.5mg daily before stopping. The estimated withdrawal time is 16 to 20 weeks or longer. .
Nitrazepam ≤10mg at night	Reduce daily dose by a quarter of a 5 mg tablet (1.25 mg) every 2 weeks. Consider nitrazepam 2.5mg/5ml liquid to achieve further reductions if needed. Target dose is 1.25mg daily dose before stopping. The estimated withdrawal time is 16 to 20 weeks or longer.
Zopiclone ≤7.5mg at night	Reduce daily dose by a half of a 3.75 mg tablet (1.875 mg) every 2 weeks. Consider conversion to diazepam 2mg/5ml to achieve further reductions if needed. Target dose is 1.875mg daily before stopping. The estimated withdrawal time is 16 to 20 weeks or longer.

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Diazepam ≤40mg/day	Reduce dose by 2–4 mg every 1–2 weeks until reaching 20 mg per day, then reduce by 1–2 mg every 1–2 weeks until 10 mg per day is reached; then reduce by 1 mg every 1–2 weeks until 5 mg per day is reached; then reduce dose by 0.5–1 mg every 1–2 weeks until completely stopped.
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- 12.1.2. Gradual withdrawal of hypnotics may be best done by a prescriber whilst a patient is undergoing CBT-I treatment. A specialist sleep clinic (e.g., UCLH insomnia clinic) or another prescriber familiar with the CBT-I programme may be able to advise on the best regime/timing for this.
- 12.1.3. If the patient requires ongoing pharmacological treatment for their insomnia (as per Section 7 and Appendix A), they may be switched to daridorexant which is now the first-line pharmacological treatment for chronic insomnia. However, daridorexant is not a hypnotic and therefore will not reduce the physiological withdrawal effects from reducing or stopping hypnotics. If the patient is likely to be physiologically dependant on benzodiazepines or z-drugs, this should be tapered gradually as described above. Additionally, daridorexant could gradually be initiated (instead of commencing at 50mg/night as is done usually, it could be commenced at 25mg and gradually increased as the benzodiazepine/z-drug is withdrawn). Since daridorexant does not act on hypnotic pathways, its effect feels different subjectively. Therefore, the patient should be counselled on this before switching to it so that their experience can be in line with their expectations.

13 ROLES AND RESPONSIBILITIES

	Role	Responsibility
1.	The Chief Executive	Overall responsibility for ensuring that mechanisms are in place for the overall implementation, monitoring and revision of policies and guidelines.
2.	Executive Director	The accountabilities of the executive director who approves the policy/ guidelines and any other executive directors with a role in the policy or guidelines
3.	Chief Pharmacist	Designated responsible person for the establishment, maintenance and monitoring of medicines optimisation and management systems for the Trust.
4.	Drugs and Therapeutics Group	Responsibilities for clinical policy and guideline approval - ensuring that the document meets the Equality Impact Assessment requirements and regulatory body criteria if appropriate before approval..
5.	Responsible Clinician	Ensure that all hypnotics are prescribed appropriately and reviewed in line with this policy.
6.	Medical prescribers and NMPs	Ensure prescribing of hypnotics considers the guidelines set out in this document.
7.	Pharmacists	Ensure the prescribing of -hypnotics is in accordance with this document, the Trust Medicines Management policy and any appropriate national guidelines.
8.	Modern matrons and service managers	Ensure that: wards/ units comply with principles set out in this document.

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	Role	Responsibility
		○ staff are experienced and /or appropriately qualified/ trained staff to carry out medication administration and monitoring process.
9.	Clinical staff	Staff are responsible for ensuring they are familiar with the content of this document and follow its requirements.

14 DISSEMINATION

- 14.1 This document will be circulated to relevant clinical staff and will be available to all staff via the Trust intranet. Managers will ensure that all staff are briefed on its contents and on what it means for them.

15 COMPLIANCE AND MONITORING

Lead	Method for monitoring compliance	Frequency	Committee or Group responsible for implementation	Committee or Board to receive assurance
Chief Pharmacist	All prescriptions for hypnotics on inpatient charts are clinically screened by a pharmacist prior to dispensing.	On-going	Drugs and Therapeutics Group	Trust Quality and Safety Group

16 REVIEW

- 16.1 The Drugs and Therapeutics Group will approve this document.
- 16.2 The guidelines will be reviewed every three years and amended as necessary. It may be reviewed before this time if for example, any new legislation, new professional guidance and/ or procedures (locally or nationally) are introduced.

17 RELATED DOCUMENTS

- Medicines Management Policy
- Rapid Tranquillisation Policy
- Anxiety Disorder Prescribing Guidelines
- BPAD Guidelines

18 SOURCES

1. Journal of Psychopharmacology 24(11) 1577-1600. available at www.bap.org.uk/pdfs/Bap_Sleep_Guidelines.pdf by S.J.Wilson
2. BNF British National Formulary. <https://bnf.nice.org.uk/> . (accessed November 2024).
3. Taylor D., Barnes T.R.E., Young A.H. Editors. The South London and Maudsley NHS Foundation Trust. Oxleas NHS Foundation Trust. Prescribing Guidelines. 14th Edition. London. Informa Healthcare. 2021.

Management of Insomnia Guidelines

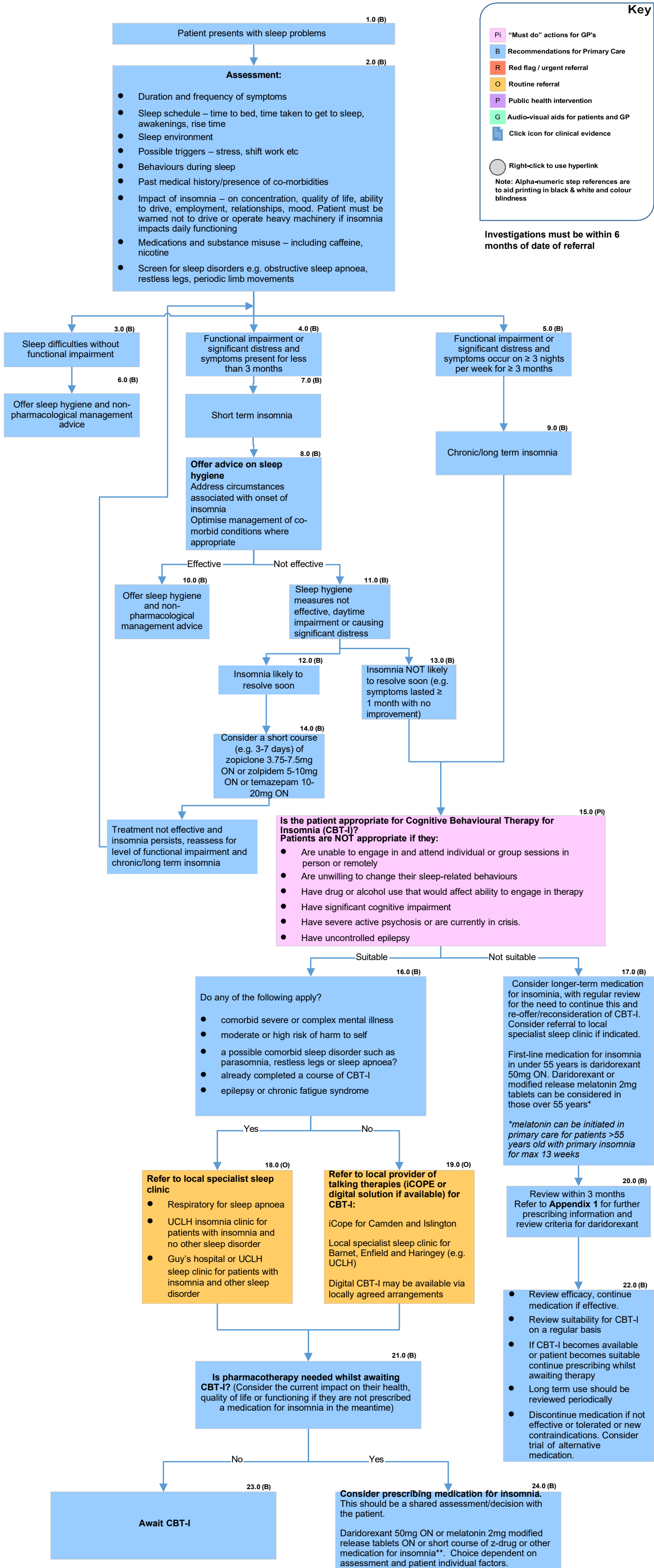
4. Electronic Medicines Compendium <https://www.medicines.org.uk/emc> (accessed November 2024).
5. Email from Jeff Halperin to Rashmika Shah. CBTi. 29 April 2014.
6. Drug Safety update. Drugs and driving: blood concentration limits to be set for certain controlled drugs in a new legal offence.(online). <https://www.gov.uk/drug-safety-update/drugs-and-driving-blood-concentration-limits-to-be-set-for-certain-controlled-drugs-in-a-new-legal-offence> (accessed November 2024).
7. Sleeping well. Royal College of Psychiatrists <https://www.rcpsych.ac.uk/mental-health/mental-illnesses-and-mental-health-problems/sleeping-well>
8. How to fall asleep faster and sleep better. <https://www.nhs.uk/every-mind-matters/mental-wellbeing-tips/how-to-fall-asleep-faster-and-sleep-better/>
9. North Central London Joint Formulary, <https://www.ncl-jointformulary.nhs.uk/>
10. NICE Final draft guidance Daridorexant for treating long-term insomnia. (September 2023) <https://www.nice.org.uk/guidance/ta922/documents/674>
11. Daridorexant for treating long-term insomnia Technology appraisal guidance Reference number:TA922 Published: 18 October 2023 <https://www.nice.org.uk/guidance/ta922/chapter/1-Recommendations>
12. British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders: An update. Journal of Psychopharmacology 2019, Vol. 33(8) 923–947. https://www.bap.org.uk/pdfs/BAP_Guidelines-Sleep.pdf
13. Insomnia: DSM-5, Categories, Comorbidities & Treatments. <https://www.medcentral.com/behavioral-mental/sleep-disorders/psychiatric-disorders-insomnia>
14. Guidance on the use of zaleplon, zolpidem and zopiclone for the short-term management of insomnia Technology appraisal guidance Reference number: NICE TA77 Published: 28 April 2004. <https://www.nice.org.uk/guidance/ta77>
15. Insomnia Guidelines. Medscape <https://emedicine.medscape.com/article/1187829-guidelines?form=fpf> (accessed November 2024)
16. The Updated European Insomnia Guideline on the Diagnosis and Treatment of Insomnia. <https://www.medscape.co.uk/viewarticle/updated-european-insomnia-guideline-diagnosis-and-treatment-2024a1000ga9> (accessed November 2024)
17. National Institute for Health and Clinical Excellence. Antenatal and postnatal mental health. Clinical management and service guidance. NICE clinical guidance 192. (updated 11th Feb 2020). <https://www.nice.org.uk/guidance/CG192> (accessed November 2024).
18. Bazire S. The Psychotropic Drug Directory: The professionals' pocket handbook and aide memoire. 2020/21.
19. Baldwin et al. Benzodiazepines: Risks and benefits. A reconsideration.2013, *Journal of Psychopharmacology* 27(11) 967–971.
20. Department of Health (England), the Scottish Government, Welsh Assembly Government and Northern Ireland Executive. Drug Misuse and Dependence. (online) Available: http://www.nta.nhs.uk/uploads/clinical_guidelines_2007.pdf (accessed 9th of December 2014).
21. National Institute for Health and Clinical Excellence. Benzodiazepine and Z-drug withdrawal. (online) Available: <https://cks.nice.org.uk/benzodiazepine-and-z-drug-withdrawa> | accessed November 2024).
22. National Institute for Health and Clinical Excellence. NICE Guidance (NG11) Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges. May 2015
23. Insomnia | Health topics A to Z | CKS | NICE [Internet]. Cks.nice.org.uk. 2022 (accessed 11 April 2022). Available from: <https://cks.nice.org.uk/topics/insomnia/>

Management of Insomnia Guidelines

24. Brigg's Drugs in Pregnancy & Lactation: Promethazine. MedicinesComplete. 2022 (accessed 12 April 2022). Available from:
<https://www.medicinescomplete.com/#!/content/dpl/Briggs-ch015-topic341?hspl=promethazine>
25. Choosing equivalent doses of oral benzodiazepines. Published 25 January 2022 · Last updated 2 June 2023 (accessed December 2024).
<https://www.sps.nhs.uk/articles/choosing-equivalent-doses-of-oral-benzodiazepines/>

APPENDIX A: North Central London Insomnia in Adults Clinical Pathway

NHS North Central London Integrated Care Board	Latest Version	Version 1.6 October 2025
	Previous Versions	V 1.5 June 2025
Insomnia in Adults Clinical Pathway	Review Date	April 2027
	Approving Body	NCL ICB Medicines CRG, NCL ICB CAG
	NCL-Wide / Borough(s)	NCL-Wide
	Author(s)	NCL insomnia working group
For any queries regarding the content of this document e-mail: nclpcb.pathways@nhs.net		



*Chronic insomnia is defined as a difficulty in initiating or maintaining sleep, despite adequate opportunity, at least 3 nights per week for 3 months, which results in daytime impairment or significant distress.

**Insomnia medication considerations – refer to Appendix A.1- medication for insomnia:

- DO NOT prescribe sedating antihistamines e.g. promethazine for management of insomnia due to high anticholinergic burden.** Promethazine is not recommended by the British Association for Psychopharmacology for the treatment of insomnia. May be considered in pregnancy.
- If another comorbidity is present (e.g. depression), consider starting a sedating antidepressant/increasing a dose of their current sedating antidepressant.
- Consider if there are any indicators that the patient may be at risk of developing misuse of sleeping tablets (e.g. past misuse on sleeping tablets or benzodiazepines, or past/current dependence on other substances). This would influence the weighing up of risks and benefits.
- Note that needing ongoing sleeping tablets does NOT always indicate dependence/'addiction'. Risk vs benefit should be assessed considering insomnia may be a chronic condition.

Appendix A.1 – Medicines for management of insomnia

Zopiclone	3.75-7.5mg ON. For short term insomnia. Should be used at lowest effective dose for short courses (e.g 3-7 days, 2-4 weeks maximum) for short term insomnia Advise patients not to drive or operate heavy machine until the effects of the medication on them are known.
Temazepam	10-20mg ON. For short term insomnia First choice benzodiazepine for insomnia in NCL. Should be used at lowest effective dose for short courses (e.g. 3-7 days, 2-4 weeks maximum) for short term insomnia
Zolpidem	5-10mg ON. For short term insomnia. Should be used at lowest effective dose for short courses (e.g 3-7 days, 2-4 weeks maximum) for short term insomnia Advise patients: - not to drive, operate machinery, or work at heights until at least 8 hours after taking zolpidem - not to take zolpidem with alcohol, illicit drugs, or other central nervous system suppressants - not to drive, operate machinery or work at heights if they are still drowsy after taking Zolpidem Use with caution in the elderly and those with liver impairment – max dose 5mg ON
Melatonin	2mg once daily, 1-2 hours before bedtime and after food. Prescribe the 2mg MR tablet as preference (prescribe generically) Can be initiated in primary care for licensed indication: as monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over for up to 13 weeks For other indications approved for use in NCL see NCL factsheet
Promethazine and other sedating antihistamines	Not recommended for the management of insomnia due to the risk of potential side-effects and anticholinergic burden. May be considered for pregnant patients although non-pharmacological measures are preferred
Daridorexant	Indicated in insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected only if: - cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or - CBT-I is not available or is unsuitable. - Can be considered if pharmacotherapy is needed whilst awaiting CBT-I 50mg ON (except in moderate liver impairment) See Appendix A.2 for further information on daridorexant
Antidepressants e.g. mirtazapine	If an antidepressant indicated for management of depression, consider a sedating antidepressant which can help with sleep
Antipsychotics e.g. olanzapine and risperidone	If an antipsychotic indicated for management of a co-morbid mental health condition, consider a sedating antipsychotic which can help with sleep

Appendix A.2 - Daridorexant tablets (Quviviq®▼) prescribing information

Daridorexant is a dual orexin receptor antagonist. Orexin neuropeptides act on orexin receptors to promote wakefulness. Daridorexant antagonises the activation of orexin receptors and thereby decreases the wake drive, allowing sleep to occur, without altering the proportion of sleep stages.

Daridorexant is licensed for the treatment of adult patients with insomnia characterised by symptoms present for at least 3 months, and considerable impact on daytime functioning.

[NICE technology appraisal \(TA\) 922](#) recommends daridorexant as an option for treating insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected only if:

- cognitive behavioural therapy for insomnia (CBT-I) has been tried but not worked, or
- CBT-I is not available or is unsuitable.

Prescribing information – refer to the [SmPC for full prescribing information](#)

Dose and administration

- The recommended dose for adults is 50 mg ON, taken orally in the evening within 30 minutes before going to bed.
- Daridorexant can be taken with or without food but taking it after a large meal may reduce its effect on sleep onset.
- Dose adjustment will be required taking moderate CYP3A4 inhibitor or who have moderate hepatic impairment (recommended dose 25mg ON). Not recommended for those with severe hepatic impairment.
- No dose adjustment required for elderly patients
- The maximum daily dose is 50 mg.
- Limited data are available in patients older than 75 years. No data are available in patients older than 85 years.

Contraindications

- Hypersensitivity to the active substance or to any of the excipients
- Narcolepsy
- Concomitant use with strong CYP3A4 inhibitors including clarithromycin, ketoconazole, itraconazole, nelfinavir, ritonavir, saquinovir, posaconazole, voriconazole, grapefruit juice

Warning and Precautions

- As grapefruit and grapefruit juice inhibit CYP3A4, the manufacturer of daridorexant recommends against consuming grapefruit or grapefruit juice in the evenings.
- Because of the general risk of falls in the elderly, daridorexant should be used with caution in this population. Research has not shown an increased risk of falls.
- Patients should be warned about engaging in potentially hazardous activities, driving, or operating heavy machinery unless they feel fully alert, especially in the first few days of treatment. A period of approximately 9 hours is recommended between taking daridorexant and driving or using machines.
- Caution should be exercised when prescribing concomitantly with CNS-depressant medicines – potential for additive effects. Other hypnotic medicines should be reviewed prior to starting daridorexant
- Patients should be counselled on the possible side-effects of treatment prior to starting treatment including possible sleep paralysis or hypnagogic/hypnopompic hallucinations
- Patients should be warned about drinking alcohol during treatment (additive effects on psychomotor performance).
- Administer with caution in patients exhibiting symptoms of depression. Isolated cases of suicidal ideation have been reported in subjects with pre-existing psychiatric conditions and/or stressful living conditions.
- Daridorexant should be used with caution in patients with severe COPD.

Assessment/review of treatment

- The length of treatment should be as short as possible.
- Response to treatment should be assessed within 3 months of starting and treatment should be stopped in people whose long-term insomnia has not responded adequately.
- At each review, reassess the patients suitability for CBT-I. If patients remain unsuitable for CBT-I, daridorexant can be continued if deemed appropriate.
- Check tolerability/presence of side-effects at each review
- If treatment is continued, assess whether it is still working at regular intervals.
- Clinical data are available for up to 12 months of continuous treatment. Treatment can be stopped without down-titration

Changing between other sedative medications and daridorexant

At the time of producing this pathway, formal guidance on how and when to change between other sedative medications and daridorexant is not yet available. Supporting information will be included once this is available.

Version 1.0

February 2024

References

Idorsia Pharmaceuticals UK Ltd. Summary of Product Characteristics for Quviviq 50mg tablets. Last updated on emc 09 Jan 24. Accessed 19 Feb 24
NHS Cheshire and Merseyside Area Prescribing Group DARIDOREXANT Tablets(Quviviq®▼) for treating long term insomnia

APPENDIX B: Equality Impact Assessment



1. Expected impact of proposal on people with protected characteristics			
Just because a policy or initiative applies to all, does not mean it will have an equal impact on all			
Characteristics	Positive	Neutral	Negative
Age	☐	X	☐
Disability	☐	X	☐
Race	☐	X	☐
Gender re-assignment	☐	X	☐
Religion/Belief	☐	X	☐
Sex (male or female)	☐	X	☐
Sexual Orientation	☐	X	☐
Marriage and civil partnership	☐	X	☐
Pregnancy and maternity	☐	X	☐
The Trust is also concerned about addressing health inequalities for other disadvantaged groups			
Carers	☐	X	☐
Part-time staff	☐	X	☐
Socio-economic	☐	X	☐
Homeless people (SUs)	☐	X	☐
Unemployed people (SUs)	☐	X	☐
Substance misuse (SUs)	☐	X	☐

2. Consideration of available data, research and information
- Use this section to demonstrate an understanding of who could be affected by the proposal. Include general population data where appropriate, and information about people who will be affected with reference to protected and other relevant characteristics. - For each evidence source and say which characteristic(s) it relates to. You can include a mix of qualitative and quantitative data e.g., from national or local research, available data. Include the main findings of any engagement and consultation - Outline whether there is any over or under representation of equality groups within relevant services - don't forget to benchmark to the local population where appropriate. - For workforce / management of change proposals you will need to look at the diversity of the affected teams using available evidence such as HR reports which shows the diversity profile of council teams and service areas. Identify any over or under-representation compared with NLMHP's population economically active citizens for different characteristics. Additional sources of useful workforce evidence include: the Employee Staff Survey Report, WRES, WDES, Gender Pay Gap Reports etc. - Where there are gaps in the evidence, or you don't have enough information about some equality groups, include an equality action to find out in question 4. This doesn't mean that you can't complete the assessment without the information, but you need to follow up the action and if necessary, review the assessment later. - If you are unable to fill in the gaps, please state this clearly with a justification. - For workforce related proposals all relevant characteristics may not be included in HR diversity reporting (e.g., pregnancy/maternity). For smaller team's diversity data may be redacted.

Management of Insomnia Guidelines

- A high proportion of not known/not disclosed may require action to address under-reporting.

	Key questions (Supports EDS Domains)	Your Response (Please reference data, research and information that you have reviewed which you have used to form your response)
2.1	What evidence, data or information have you considered to determine how this policy/development contributes to delivering better health outcomes for all and improving patient access and experience??	Guidance on the use of zaleplon, zolpidem and zopiclone for the short-term management of insomnia Technology appraisal guidance Reference number: NICE TA77 Published: 28 April 2004. https://www.nice.org.uk/guidance/ta77 National Institute for Health and Clinical Excellence. Benzodiazepine and Z-drug withdrawal. (online) Available: https://cks.nice.org.uk/benzodiazepine-and-z-drug-withdrawal accessed November 2024). British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders: An update. Journal of Psychopharmacology 2019, Vol. 33(8) 923–947
2.2	What evidence, data or information have you considered to determine how this development/policy contributes to delivering a representative and well supported workforce?	N/A
2.3	What evidence, data or information have you considered to determine how this policy/guide/development contributes to inclusive leadership and governance?	N/A

3. What involvement and consultation has been done in relation to this 'policy'? (e.g., with relevant groups and stakeholders)	
Response	Detail of involvement and consultation
Trust wide engagement with senior nurses, consultants and pharmacy staff	Review and feedback comments
Drugs and Therapeutics Group	Review and feedback comments

4. Equality Impact Assessment Improvement Plan
If your analysis indicates some negative impacts, please list actions that you plan to take as a result of this analysis to reduce those impacts or rebalance opportunities. • These actions should be based upon the analysis of data and engagement, any gaps in the data you have identified, and any steps you will be taking to address any negative impacts or remove barriers. • The actions need to be built into your service planning framework. • Actions/targets should be measurable, achievable, realistic and time framed.

Management of Insomnia Guidelines

Group	Potential positive, neutral and/or negative impacts identified	Actions to mitigate any negative impact or enhanced policy	By whom
Age	Na		
Disability	Na		
Race	Na		
Gender re-assignment	Na		
Religion/ Belief	Na		
Sex (male or female)	Na		
Sexual Orientation	Na		
Marriage and civil partnership	Na		
Pregnancy and maternity	Na		
Carers	Na		
Serving or ex serving members of the Armed Forces	Na		
Socio-economic (deprivation)	Na		
Vulnerable groups (homeless, unemployed, substance misuse)	Na		

5. Sign off and publishing

1. If this Equality Impact Analysis (EIA) relates to a policy, guide, procedure or protocol, please attach it to the policy/guide and process it through the normal approval process.
2. EIA's need to be accessible as they may be requested to support Freedom of Information (FOI), for publication on the Trust website, by the Equality, Diversity and Inclusion (EDI) Team requests or by the public or any other organisations etc. So, please ensure that your EIA's are stored in your department's shared folder.
3. Once you have completed this form, you need to sign it and state the name of the accountable manager, Head of Service or Director where appropriate.
4. The email for support to complete your EIA or for queries is:

beh-tr.equalityimpactassessments@nhs.net

This email address is Partnership wide for both BEH and C&I.

Name/s, job title/s and contact/s details of person/s completing this assessment

Name: JANE MORIBA	Position and Division: EDUCATION, TRAINING & POLICY LEAD PHARMACIST
Signed: 	Date: 04/11/25

Name, job title and contact details of accountable person

Name: DR LUCINDA DONALDSON	Position: CHAIR OF DRUGS AND THERAPEUTICS
Signed: 	Date: 04/11/25