Insomnia Formulary Guidance [v1.0]

1. Introduction

These Guidelines are intended for routine use. However there will be instances where they are not suitable for the patient you are managing, where more bespoke treatment will be necessary. In such instances the rationale for prescribing away from formulary must be recorded.

Insomnia is difficulty in getting to sleep, difficulty staying asleep, early wakening, or non-restorative sleep despite adequate time and opportunity to sleep, resulting in impaired daytime functioning, e.g. poor concentration, mood disturbance, and daytime tiredness. Insomnia can be classified as follows, according to cause:

- Transient insomnia may occur in those who normally sleep well and may be due to an alteration in the conditions that surround sleeping eg noise, or secondary to workpatterns changing, travel. It may also be associated with acute conditions, often lasting on 1 – 4 weeks.
- Primary insomnia is insomnia that occurs when no co morbidity is identified. Commonly the person has conditioned or learned sleep difficulties, with or without heightened arousal in bed.
- Secondary or chronic insomnia occurs as a symptom of, or is associated with, other conditions, including medical or psychiatric illness, or substance misuse. Often this can be long term in nature

2. Non- Pharmacological Treatment – Key Points

Management of insomnia requires resolution of any stressful precipitant or identification and treatment of underlying causes. Prescribers should routinely provide information on promotion of good sleep habits (sleep hygiene) to make people aware of behavioural, environmental, and temporal factors that may be detrimental or beneficial to sleep.

General tips to help with sleep include :

- Establish fixed times for going to bed and waking up (never sleep in the day and avoid sleeping in after a poor night's sleep)
- Try to relax before going to bed – warm drink, hot bath, reading or a relaxation tape may help
- Maintain a comfortable sleeping environment: not too hot, cold, noisy or bright.
- Avoid stimulants such as caffeine and nicotine in the evening. (Consider complete elimination of caffeine from the diet, but be aware of withdrawal effects)
- Avoid exercise within 4 hours of bedtime (although exercise earlier in the day is beneficial.)
- Avoid eating a heavy meal late at night

3. Pharmacological Treatment – Key Points

3a Hypnotics

- There is good evidence for the efficacy of hypnotic drugs in short-term insomnia but they do not treat any underlying cause.
- Their use is associated with adverse effects, such as daytime sedation, poor motor concentration and cognitive impairment. In older people, in particular, the magnitude of the beneficial effect of hypnotics may not justify the increased risk of adverse effects (ie falls and cognitive impairment).
- Non-pharmacological measures should be considered before prescribing hypnotics.
- Hypnotic medication should only be initiated when non-pharmacological interventions have been unsuccessful for managing severe insomnia and after discussion with the

- service user.
- Hypnotics should be prescribed at the lowest effective dose for as short a period as possible, in strict accordance with their licensed indications.
- In transient insomnia, one or two doses of a short-acting hypnotic may be indicated; whereas in short term insomnia intermittent dosing of a short acting hypnotic given for no more than 3 weeks may be appropriate. Chronic insomnia rarely benefits from the routine use of hypnotics, and should where possible be avoided. Tolerance develops quickly (3 – 14 days continuous use), and withdrawal after long term use, can lead to rebound insomnia and other withdrawal problems.
- A number of hypnotic drugs are licensed for the treatment of insomnia, including the benzodiazepines (temazepam) and Z-drugs (zopiclone, zolpidem and zaleplon)
- Benzodiazepines are effective but many people develop tolerance to their effects, gain little therapeutic benefit from chronic use, and become both physically and psychologically dependant on them after 2-4 weeks of regular use.
- A withdrawal syndrome (anxiety, depression, nausea and perceptual changes) which may be prolonged is associated with discontinuation. This can lead to insomnia which is worse than the original symptoms.
- Due to problems with misuse, benzodiazepines should be avoided in patients with a history of substance misuse. The MHRA (CSM) advise that they should only be used to treat insomnia only when it is severe, disabling or subjecting the individual to extreme distress. The lowest dose should be used and should not continue beyond four weeks.

3b. The 'Z drugs'

- Zaleplon, zolpidem and zopiclone (the Z-drugs) are non-benzodiazepine hypnotics. They differ structurally from the benzodiazepines.
- Manufacturer summaries of product characteristics (SPCs) state: long-term continuous use is not recommended; a course of treatment should not exceed four weeks during a single period. The SPC's carry a warning of the potential to cause dependence, tolerance and withdrawal symptoms
- NICE guidance is available on zaleplon, zolpidem, and zopiclone in the short term
- management of insomnia (NICE TA77, April 2004). Key points are:
    - After careful consideration of non-pharmacological measures, hypnotic drug therapy may be considered appropriate, but should be prescribed for short periods of time only, in line with their licence.
    - Due to lack of compelling evidence to distinguish between the z-hypnotics, the drug with the lowest acquisition cost should be prescribed.
    - Switching between these hypnotics should only occur if the service user experiences adverse effects considered to be directly linked to the agent used.
    - Service users who have not responded to one of these hypnotic drugs should not be prescribed any of the others.

References

1. NICE(2004) Guidance on the use of zaleplon, zolpidem and zopiclone for the short- term management of insomnia: Technology Appraisal 77 http://guidance.nice.org.uk/TA77
2. Prodigy Guidance - Insomnia - http://prodigy.clarity.co.uk/insomnia#
3. SPC www.emc.medicines.org.uk
4. BNF 64th eds. Available online at: http://www.bnf.org

Table 1: PHARMACOLOGICAL TREATMENTS FOR INSOMNIA

First Line:	Relative Cost	Notes
Zopiclone	£	3.75-7.5mg at bedtime when required. Older adults and hepatic and renal impairment - 3.75mg tablet at night when required Use for a short period of time only in strict accordance with the licensed indications Non-pharmacological measures should be considered before drug therapy for insomnia.
Second Line:	**Relative Cost**	**Notes**
Zolpidem	£	10mg at night when required; Older adults and hepatic and renal impairment: 5mg at night when required The only acceptable reason to change hypnotics should be intolerance to the current drug.
Zaleplon	££	Very short acting due to very short half life; effects on sleep will rapidly wear off The only acceptable reason to change hypnotics should be intolerance to the current drug.
Temazepam	££	10mg at night when required; Scheduled 3 controlled drug. Subject to storage, prescribing and record-keeping requirements. To be used if Z-drugs are not suitable or tolerated. Not to be used if there is history of substance misuse due to risk of dependence and tolerance.
Not Recommended	**Relative Cost**	**Notes**
Antihistamines	£	Use of these agents for their sedative effects is not supported by evidence.
Antidepressants	£-£££	Potential for side effects such as daytime sedation, cognitive impairment and falls is significant.
Antipsychotics	£-£££	Antihistamine may cause troublesome antimuscarinic effects
Long-acting Benzodiazepines	£	Benzodiazepines with longer half-lives may cause hangover effects;
Clomethiazole	££	
Chloral hydrate	££	
Melatonin MR	£££	* licensed for >55yrs. Exception for CAMHS

TABLE 2: DRUG SPECIFIC INFORMATION

Hypnotic drug	License	Cautions	Key side-effects
Zopiclone	Short term treatment of insomnia, transient, situational or chronic insomnia and insomnia where the insomnia is debilitating or is causing severe distress for the patient. **Duration of treatment should not usually vary from a few days to 2 weeks** with a maximum of 4 weeks.	Use lower doses in renal/hepatic impairment and older adults Avoid in severe hepatic impairment and respiratory insufficiency	Bitter or metallic taste; nausea, dizziness, drowsiness, dry mouth, nightmares, rarely lightheadedness, confusion and ataxia
Zolpidem	Short term treatment of insomnia where the insomnia is debilitating or causing severe distress. **Duration of treatment should usually vary from a few days to 2 weeks** with a maximum of 4 weeks.	Use lower doses in renal/hepatic impairment and older adults Avoid in severe hepatic impairment and respiratory insufficiency	Diarrhoea, nausea, vomiting, dizziness, headache, drowsiness, fatigue, confusion, agitation, nightmares, amnesia; ataxia, falls, sleep walking
Zaleplon	Treatment of insomnia in people who have difficulty falling asleep only when the disorder is severe, disabling or subjecting the individual to extreme distress. Duration of treatment should be as short as possible with a maximum duration of two weeks.	Use lower doses in renal/hepatic impairment and older adults Avoid in severe hepatic impairment and respiratory insufficiency	Nausea, drowsiness, amnesia, paraesthesia, dizziness, sleep walking, dysmenorrhea, confusion, impaired concentration, depression
Temazepam	Short term treatment of insomnia – up to 4 weeks. Treatment should be at the lowest dose possible.	Caution in renal/hepatic impairment use low doses and avoid in severe hepatic impairment.	Drowsiness, light headedness the next day, confusion and ataxia (elderly), amnesia and dependence.
Melatonin	Patients aged over 55, as monotherapy for up to 13 weeks for primary insomnia.	Not recommended in hepatic/renal impairment Alcohol- reduces effect of melatonin on sleep.	Abdominal pain, dyspepsia, irritability, dizziness, dry mouth, migraines, constipation, stomach pain and weight gain.