Guidance on Appropriate and Cost-effective Prescribing of Short Acting Hypnotics

Insomnia is a common complaint and non-drug measures such as advice on bedtime routine and relaxation techniques are advocated for the initial management. Hypnotics can be prescribed for up to 2 weeks only after non-drug measures have failed and the patient’s insomnia is severe, disabling or causing the patient extreme distress. The purpose of this guidance is to offer advice to prescribers on managing new patients with insomnia; recommend cost-effective prescribing choices; and encourage reviewing chronic hypnotic users with a view to helping them withdraw from treatment.

Recommendations

Non-drug therapy

- “Sleep hygiene” aims to make people more aware of behavioral, environmental and temporal factors that may be detrimental or beneficial to sleep.
- In line with NHS CKS for new patients, prior to hypnotic drug therapy offer non-drug measures such as a good “sleep hygiene” guide by advising patients to:
  - Establish fixed time for going to bed and waking up (avoid sleeping in after a poor night’s sleep).
  - Try to relax before going to bed.
  - Maintain a comfortable sleeping environment: not too hot, cold, noisy or bright.
  - Avoid napping during the day.
  - Avoid caffeine, nicotine, and alcohol within 6 hours of going to bed.
  - Consider complete elimination of caffeine from diet.
  - Avoid exercise within 4 hours of bedtime (although exercise earlier in the day is beneficial).
  - Avoid a heavy meal late at night.
  - Avoid watching or checking the clock throughout the night.
  - Only use the bedroom for sleep and sexual activity.

Hypnotic Drug therapy

- Should a prescription be considered appropriate if non-drug measures have failed, use a hypnotic at the lowest dose and for up to 2 weeks only, in strict accordance with their licensed indications. Prescribers should familiarise themselves with the hypnotic drug indication, dose, administration, contra-indications, cautions, side-effects, interactions and preparation by referring to the current version of the Summary of Product Characteristics (SPC) (http://www.medicine.org.uk/emc/default.aspx) or the BNF (http://www.medicinescomplete.com/mc/index.htm).
- With respect to hypnotic action there is lack of compelling evidence between benzodiazepines and Z-drugs (zopiclone, zolpidem and zaleplon). Choosing non-benzodiazepine Z-drugs has advantages in terms of unintended side effects such as tolerance, dependence, cognitive impairment and increased risk of falls.
- If a patient does not respond to one Z-drug, do not switch to another hypnotic in an attempt to get a response as there is no evidence to suggest that switching works.
- Switching should only be considered if a patient experiences adverse effects directly related to a specific agent.
- Melatonin may appear to be an attractive option where there is a concern of dependence but the treatment effect is small and is more expensive than other hypnotics.
• Also according to WSCCG Traffic Light System (TLS) melatonin (Circadin®) is:
  ▪ double red drug (no prescribing) for patients aged 55 years and older
  ▪ amber drug (shared care prescribing under shared care agreement) for children and adolescents.

Hypnotic Withdrawal

• Development of tolerance, dependence potential and withdrawal causing rebound insomnia are well known problems associated with benzodiazepines and Z-drugs. Problems are less likely if withdrawal is slow, patient-led and well supported.

• The benzodiazepine withdrawal syndrome may develop at any time up to 3 weeks after stopping a long-acting benzodiazepine, but may occur within a day in the case of a short-acting one. A suggested protocol for withdrawal for prescribed long-term benzodiazepine patients is described in the British National Formulary (BNF)\(^5\) (https://www.medicinescomplete.com/mc/bnf/current/PHP2093-hypnotics-and-anxiolytics.htm)

• For chronic hypnotic users, the need for a hypnotic should be reviewed. A support for gradual withdrawal from hypnotic should be offered using techniques such as patient letters from the General Practitioner (GP) explaining the disadvantages of regular use of hypnotics\(^3\).

• A shared care approach with specialist advice from Suffolk Recovery Network, Turning Point\(^4\) may be required for more complex patients with:
  ▪ a history of drug use or dependence
  ▪ a history of drug withdrawal seizures - these generally occur in people who suddenly stop high doses of the drugs. Slow tapering is recommended for these individuals.

\(^4\)Suffolk Recovery Network, Turning Point (Suffolk@turning-point.co.uk) 03001230872.

• The ALL Wales Medicine Strategy Group (AWMSG)\(^4\) comprehensive educational pack with “best practice” examples for prescribers to support problem of long term hypnotics and anxiolytics is available at www.wales.nhs.uk/sites3/page.cfm?orgid=371&pid=53297.

Hypnotic Product Comparisons\(^1\)

Table 1: provides a comparison between short acting benzodiazepines, Z-drugs and melatonin modified release (MR).

<table>
<thead>
<tr>
<th>Hypnotic</th>
<th>Drug Class</th>
<th>Duration of Effect</th>
<th>Dose</th>
<th>Licensed length of treatment</th>
<th>Cost per pack (October 2015 Drug Tariff)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zopiclone tablets</td>
<td>Z-drug</td>
<td>Short acting</td>
<td>7.5mg (bedtime)</td>
<td>Few days to 2 weeks, max 4 weeks including tapering off.</td>
<td>£1.56</td>
</tr>
<tr>
<td>Zolpidem tablets</td>
<td>Z-drug</td>
<td>Short acting</td>
<td>10mg (bedtime)</td>
<td>Few days to 2 weeks, max 4 weeks including tapering off.</td>
<td>£1.48</td>
</tr>
<tr>
<td>Temazepam tablets</td>
<td>Benzodiazepine</td>
<td>Short acting</td>
<td>10-20mg (bedtime)</td>
<td>Not exceeding 4 weeks</td>
<td>10mg - £8.10 20mg - £8.34</td>
</tr>
<tr>
<td>Zaleplon capsules</td>
<td>Z-drug</td>
<td>Very Short acting</td>
<td>10mg (bedtime)</td>
<td>Maximum 2 weeks</td>
<td>£3.76</td>
</tr>
<tr>
<td>Melatonin MR tablets</td>
<td>Pineal hormone</td>
<td>Short acting (MR formulation only)</td>
<td>2mg (1-2hrs before bedtime for over 55 yrs)</td>
<td>Maximum 13 weeks</td>
<td>£15.39</td>
</tr>
<tr>
<td>Loprazolam tablets</td>
<td>Benzodiazepine</td>
<td>Short acting</td>
<td>1mg (bedtime) – increase to 1.5 - 2mg if needed</td>
<td>Maximum 4 weeks</td>
<td>1mg - £18.00</td>
</tr>
<tr>
<td>Lorormetazepam tablets</td>
<td>Benzodiazepine</td>
<td>Short acting</td>
<td>0.5-1.5mg (bedtime)</td>
<td>Few days to 2 weeks, max 4 weeks including tapering off.</td>
<td>0.5mg - £20.88 1.5mg - £23.68</td>
</tr>
</tbody>
</table>

References:
1. PrescQIPP bulletin 41 appropriate and cost-effective prescribing of short acting hypnotics.
2. NHS Clinical Knowledge Summaries (CKS), Insomnia – Management. What advice should I give regarding good sleep hygiene. Available at https://cks.nice.org.uk/insomnia#scenario_recommendation:2
5. NHS BSA, Electronic Drug tariff October 2015 (http://www.drugtariff.nhsbsa.nhs.uk)