HYPNOTICS PRESCRIBING GUIDANCE

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HYPNOTICS PRESCRIBING GUIDANCE

1 INTRODUCTION

1.1 This guidance applies to all doctors, practice nurses and practice staff involved in the issue of prescriptions.

2 PURPOSE

2.1 To clearly support the practice’s policy on the prescribing of hypnotics for the treatment of insomnia.

2.2 To reduce the use of hypnotics, with the ultimate aim of eradicating inappropriate and/or long-term use and only allowing prescribing by clinicians at the practice for short-term courses in cases of severe debilitating insomnia.

2.3 To improve the rigour and quality of the prescribing decision in respect of hypnotic prescribing.

2.4 To clarify what hypnotics can and cannot be prescribed, by whom, and in what circumstances.

3 AIMS

3.1 This guidance has the aspiration of creating a culture in GP practices where:

- All patients presenting with sleep problems are given appropriate advice on the incidence of sleep problems and advised on self-help measures.
- Sleep problems caused or exacerbated by the side-effects of other medication are minimised or eradicated.
- First-line treatment of sleep problems is non-pharmacological.
- Prescribing of hypnotics is reserved for short-term treatment of severe debilitating insomnia and conforms to the relevant NICE guidance.
- Prescriptions for hypnotics never exceed 14 days’ duration of treatment except for palliative care (specific partnership shared care patients) where appropriate.
- All hypnotic prescribing is within the licensed indications of the medication prescribed.
- There is no prescribing of hypnotics on a long-term or regular basis to the same patient except for palliative care/specific partnership shared care patients.
- Hypnotics will only be prescribed to the elderly in exceptional circumstances.
• No hypnotic prescribing inadvertently results in patient harm.
• All interventions and consultations will be documented in the patient’s notes and appropriately READ coded.
• The practice can demonstrate, upon request, its compliance with the standards set out below.

4 SCOPE

4.1 This guidance applies to the prescribing of hypnotics to adults by GPs, locums, and non-medical prescribers at the practice. The guidance also covers procedures conducted by practice staff involved in the generation of prescriptions.

4.2 This guidance does not cover the prescribing of hypnotics or sedatives to children or adolescents.

5 BACKGROUND

5.1 NICE guidance states:

When, after due consideration of the use of non-pharmacological measures, hypnotic drug therapy is considered appropriate for the management of severe insomnia interfering with normal daily life, it is recommended that hypnotics should be prescribed for short periods of time only, in strict accordance with their licensed indications.

5.2 Hypnotics - for the purpose of the guidance this refers to Benzodiazepines and Z-drugs (Zapelon, Zopiclone, and Zolpidem) - are drugs of limited use in the management of insomnia and are also potentially harmful in respect of their potential for dependence, both physical and psychological, high side-effect profile and for being a potential risk factor in elderly falls.

5.3 Sometimes the situation arises whereby patients may request a “past drug”. This may get printed then signed by the doctor without enough thought having been given to the merits or otherwise of restarting the medication. Improving the rigour of the prescription issue process will improve the quality of the prescribing decision.

5.4 It is recognised that a number of patients have been prescribed hypnotics over the long-term and will now be dependent on the medication. Hypnotics will often have been initiated by colleagues in other practices or by predecessors prior to the risks of hypnotic treatment being fully identified. These patients must be identified in practice lists and encouraged to engage in a managed reduction of hypnotic use and dependence with the eventual intention of achieving withdrawal.

5.5 Practice staff involved in the processing of patients’ repeat prescription requests are key members of the practice team for identifying some of the issues highlighted above and bringing them to the relevant doctor’s attention in a timely manner.
STANDARDS

- Patients presenting with sleep problems must always be given the “Essential Information for Patients” (see section 7.1 below).
- Assessment must include a full sleep history from the patient, examination of mental state and review of medical, psychiatric and family histories.
- Existing medication for other conditions must be reviewed and amended if appropriate to minimise contribution to sleep problems.
- Non-pharmacological treatments must always be considered first-line.
- Initiation or re-starting hypnotics is only allowed by doctors after careful assessment of the patient’s current clinical needs.
- Treatment with hypnotics should be for short duration only. Prescriptions must be for a maximum of 14 days’ of medication. The only exception to this is in cases of palliative care/specific partnership shared care patients where informed consent has been received.
- Prescriptions for hypnotics will never be added to “repeat” medication; treatment must remain in “Acute” drugs.
- All prescriptions for hypnotics must have explicit dosage instructions. “As directed” or similar is not acceptable.
- The most cost-effective hypnotic (benzodiazepine or Z-drug) should be prescribed (refer to the PCT formulary for the current recommendations).
- Reasons for initiation of hypnotic medication must be fully documented in the patient’s notes with explicit reference to informed consent having been given by the patient.
- Temporary residents will only be prescribed hypnotics after confirmation of treatment has been received from the patient’s registered doctor. Temporary residents will only be issued with prescriptions for hypnotics for a minimum duration of treatment up to a maximum of seven days’ treatment.
- Nitrazepam should rarely be prescribed and never in the elderly.
- Chlomethiazole must only be prescribed for the treatment of alcohol withdrawal symptoms in line with the relevant NICE guidance.
- Melatonin is not recommended for insomnia or jet-lag (unlicensed use).
- Low dose tricyclic antidepressants, eg. amitriptyline 10mg, should not be prescribed as a hypnotic.
GUIDANCE ON PRESCRIBING HYPNOTICS

7.1 Essential information for patients:

- Temporary sleep problems are common and do not require treatment.
- People vary in the amount of sleep they need.
- Temporary sleep problems may be the result of a change in lifestyle or circumstances (e.g., after long-distance travel, moving house, a change in working hours) - generally the body will take about three days to reset its sleep pattern.
- If insomnia lasts more than a few days, advice should be sought and the cause identified (most causes are treatable).
- Generally avoid:
  * self-medication with over-the-counter drugs.
  * taking someone else’s medication.
  * using alcohol to sleep better.
  * taking sleeping pills for more than a few days (and preferably not at all).
  * lying awake in bed for long periods.

7.2 Initial assessment:

- Assessment should include a full sleep history from the patient (also bed partner, family, etc if possible), examination of mental state and review of medical, psychiatric and family histories.
- Screening sleep questionnaires and a sleep diary can be valuable.

7.3 Before considering initiating a pharmacological treatment for insomnia:

- Review the patient’s current medication for drugs that may be causing or contributing to sleep problems - consider adjusting existing treatment regimes to minimise disturbance to the patient’s sleep.
- Encourage the patient to practise good sleep hygiene:
  * Keep to regular hours for going to bed and getting up in the morning, including at weekends.
  * Make plans or think about problems before retiring to bed.
  * Keep a pen and pad next to the bed for writing down troublesome thoughts which can then be reviewed.
  * Avoid caffeine, stimulant/energy drinks and alcohol in the evenings.
  * Avoid daytime naps.
  * Daytime exercise can help the patient to sleep regularly, but evening exercise may contribute to insomnia.
• Remember: Behavioural treatment is safer and more effective than medication (eg. cognitive therapy, stimulus control, sleep restriction, relaxation).

• Self-help leaflets, books and groups may be useful.

• Discuss with the patient:
  * the risks and benefits of treatment.
  * that the treatment will be time-limited to a single short-term course only.
  * that if treatment with one hypnotic is unsuccessful trying a different hypnotic is very unlikely to succeed hence repeated attempts with different drugs is not part of the treatment plan.

• Consider asking the patient to keep a sleep diary to assist in assessment and monitoring of progress.

• In the case of Temporary Residents, the patient’s registered doctor must be contacted to confirm treatment is clinically appropriate and necessary.

7.4 Only consider pharmacological treatment for insomnia after the above advice, then:

• Address underlying psychosocial, psychiatric or physical conditions.

• Make changes to existing medication, as appropriate.

• A brief, time-limited use of hypnotic medication may sometimes be useful.

7.5 Patients on existing long-term hypnotic treatment:

• Patients who are found to have been on long-term hypnotic treatment must have their treatment periodically reviewed in a consultation with a healthcare professional.

• For new patients, registering with the practice provides an ideal opportunity for medication review and addressing the issue of long-term hypnotic treatment.

• Patients must periodically be offered the opportunity to reduce their use of hypnotics in a managed way with the aim of complete eventual withdrawal.

• Long-term treatment will only be continued for patients where informed consent has been received and documented in the patient notes.

• Patients on long-term hypnotic therapy must also have hypnotics in “Acute” drugs. Hypnotics must not be on “repeat” even for patients on long-term treatment.
• Practice staff must be especially vigilant when processing prescriptions for patients on long-term hypnotics and must flag up to doctors any over-ordering by patients to prevent any creeping reduction in prescribing interval.

• Prescribers may authorise issue of prescriptions early if mitigating circumstances exist (eg. patient holiday etc) but date for the resumption of the “normal” prescribing cycle must be explicitly documented (ideally in the dosage instructions of the prescription) to prevent over-ordering by the patient.

7.6 Starting from the principle that hypnotics should not be routinely prescribed for patients complaining of insomnia then consider the following action points:

• Use of self-help leaflets/information sheets is useful and recommended.

• There is evidence that in people older than 60 years, benzodiazepines, other sedatives and hypnotics, and antidepressants are associated with an increased risk of falling of around 50-70% in relative terms.¹

• Anxiolytic or hypnotic drugs have been reported² to increase the mortality rate to 15.7 per cent compared to 10.5 per cent for those who had not taken these medicines.

• If initiation of hypnotics is clinically indicated and appropriate a maximum of two weeks’ (14 days’) supply of hypnotic medication is only to be issued. Remember: tolerance can develop in as little as three days of continuous use.

• NICE recommends that, because of the lack of compelling evidence to distinguish between the Z-drugs or the shorter-acting benzodiazepine hypnotics, the drug with the lowest purchase cost (taking into account daily required dose and product price per dose) should be prescribed.

• Switching from one hypnotic to another should only occur if a patient experiences adverse effects considered to be directly related to a specific agent. These are the only circumstances in which the drugs with the higher acquisition costs can be considered.

• Patients who have not responded to one hypnotic drug should not be prescribed any others. There is no evidence to suggest that if a patient is unresponsive to one hypnotic drug they will to respond to another.

• A hypnotic must never be added to a repeat medication.

A hypnotic must never be re-started from “past drugs” by non-medical practice staff. Hypnotics can only be reinstated from past drugs by a doctor after careful re-assessment of the patient’s clinical needs.

If prescribing for patients on long-term hypnotics (due to historical prescribing practices by colleagues or predecessors) prescribers should be careful to prevent over-ordering even by one or two days. Prescribers should also be mindful of the potential for diversion/illegal sale of hypnotics.

Temazepam is a Schedule 3 controlled drug and therefore can only be prescribed by non-medical prescribers when acting in a Supplementary Prescriber capacity.

Nitrazepam should only be prescribed in exceptional circumstances and never in the elderly due to its long half-life and higher incidence of a “hang-over” effect.

Expensive hypnotics, eg. lormetazepam and loprazolam are not considered a cost-effective use of NHS resources and therefore should not be prescribed.

Melatonin is not recommended for insomnia on the basis of lack of evidence as a cost-effective product. Melatonin is only available in one licensed product, Circadin®, which has limited licensed indications (short-term use in patients over 55 years only).

Low dose tricyclic antidepressants should not be prescribed as a hypnotic eg. amitriptyline 10mg.

Remember: insomnia could be part of a wider clinical picture, eg. depression.

With regard to existing repeat prescriptions of hypnotics and other benzodiazepines (eg. Diazepam), these should be actively reviewed and the medical notes annotated to indicate the need to continue the repeat nature of the prescription.

8 GUIDANCE ON THE PROCESSING, BY PRACTICE STAFF, OF PRESCRIPTION REQUESTS FOR HYPNOTICS:

8.1 Practice staff must:

- Never re-start a hypnotic from “past drugs”.
- Never move hypnotic medication from “acute” to “repeat” medication.
- Pass all requests from patients for a hypnotic in “past drugs” to a doctor for re-assessment of the patient’s clinical need.
• Refer hypnotics on “repeat” medication to the relevant doctor highlighting that this is against practice policy.

• Treat all prescriptions for hypnotics as “acute” medication that requires referral to the relevant doctor before a repeat issue can be actioned.

• Report all over-ordering requests for hypnotics to the relevant prescriber.

• Highlight patients due for a review of their hypnotic medication to the relevant doctor on each occasion of a prescription request.

• Query with the relevant doctor any hypnotic prescription:
  * issued to a temporary resident that exceeds seven days’ duration of treatment.
  * issued to a registered patient that exceeds 14 days’ duration of treatment except in cases of palliative care.
  * that does not have explicit dosage instructions.

9  AUDIT

9.1 The practice should measure its performance against the standards set out in this guidance prior to the adoption of the guidance to provide baseline data for future audit.

9.2 The practice will periodically (nominally every year) audit its performance against the standards. Action plans will then be drawn up to address specific areas that may need attention.

9.3 Through the audit process, the practice would hope to be meeting a majority of the aspirations set out in the Aims above within five years.

10  REVIEW

10.1 This guidance will be reviewed every two years.

11  ACKNOWLEDGEMENT

11.1 This guidance was adapted and expanded from a policy written by Dr Harvey Sampson of Burnham Medical Centre. We are indebted to Dr Sampson and Burnham Medical Centre for allowing the use of their original policy.