



SEDATIVE HYPNOTICS

Ambien (zolpidem), Ambien CR (zolpidem extended-release), Dalmane (flurazepam), Doral* (quazepam), Edluar (zolpidem sublingual), Halcion (triazolam), Intermezzo (zolpidem sublingual) Lunesta (eszopiclone), Prosom (estazolam), Restoril (temazepam), Sonata (zaleplon), Zolpidem capsule*, Zolpimist (zolpidem) Oral Spray

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Insomnia is defined as complaints of disturbed sleep in the presence of adequate opportunity and circumstance for sleep. The disturbance can consist of one or more of three features: difficulty in initiating sleep; difficulty in maintaining sleep; or waking up too early. Insomnia can be primary or secondary to a variety of medical illnesses, psychiatric disorders, or drug use. Identifying and treating potential underlying conditions or comorbid diagnoses are priorities in the treatment of insomnia. In order to treat insomnia, various treatment modalities should be considered, such as sleep hygiene, sleep restriction, stimulus control and cognitive behavioral therapy, prior to the addition of pharmacotherapy, and continued throughout pharmacotherapy treatment (1-2).

The treatment of insomnia should be individualized and is dependent on the differential diagnosis. Although short-term therapy is appropriate for most patients, some patients may benefit from long-term use. Patients with insomnia that occurs several days per week and lasts for more than a month may have the diagnosis of chronic insomnia. There are indications that long-term management of chronic insomnia may be beneficial. Long-term management of chronic insomnia is achievable when pharmacotherapy is considered for use only in response to the occurrence of the symptoms, thus permitting long-term therapy without the use of nightly medication (1).

Regulatory Status

FDA -approved indication: Sedative hypnotics are indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation (2-15).

Use of sedative-hypnotics can cause serious side-effects including cognitive impairment, rebound insomnia, morning sedation, falls and dependence (2).

Non-pharmacologic interventions have been shown to produce consistent and sustained improvements for insomnia. These approaches include sleep hygiene, stimulus control, sleep



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restriction, paradoxical intention, and relaxation therapy (2).

Some of the sedative hypnotics have a boxed warning regarding complex sleep behaviors, including sleep-walking, sleep-driving, and engaging in other activities while not fully awake. Discontinue sedative hypnotics immediately if a patient experiences a complex sleep behavior (3-15).

Summary

Insomnia is defined as complaints of disturbed sleep in the presence of adequate opportunity and circumstance for sleep. The disturbance can consist of one or more of three features: difficulty in initiating sleep; difficulty in maintaining sleep; or waking up too early (1).

The treatment of insomnia should be individualized and is dependent on the differential diagnosis. Although short-term therapy is appropriate for most patients, some patients may benefit from long-term use. Patients with insomnia that occurs several days per week and lasts for more than a month may have the diagnosis of chronic insomnia. Use of sedative-hypnotics can cause serious side-effects including cognitive impairment, rebound insomnia, morning sedation, falls and dependence (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Sedative Hypnotics while maintaining optimal therapeutic outcomes

References

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