

Updates for Insomnia: Evidence and Oregon Medicaid Policy

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Insomnia is defined as the subjective perception of difficulty with sleep which occurs despite adequate opportunity for sleep and causes functional impairment during the day.^{1,2} It is estimated that about 5-10% of people experience chronic insomnia.² This newsletter will summarize the evidence for insomnia treatments and describe new policy changes for Oregon Medicaid.

Treatment Factors to Consider

Insomnia is often classified as short-term (typically <3 months in duration with an identifiable stressor), long-term (i.e., chronic; (occurring ≥3 times per week for >3 months) or other (if criteria for short- and long-term criteria are not met). Insomnia is more common in elderly, females, individuals who are divorced or separated, those with shift work, and patients with lower socioeconomic status.³ Insomnia symptoms have been associated with reduced health-related quality of life and cognitive decline in patients over 65 years of age.³ Insomnia can also worsen outcomes for patients with comorbid conditions including cardiovascular disease, post-traumatic stress disorder, and depression.³ Because insomnia may be associated with a wide variety of medical and psychological conditions, identification and treatment of contributing factors and comorbid conditions (such as medical conditions, substance misuse, and psychiatric conditions) is important for management of insomnia.¹

Treatments for Insomnia

Cognitive Behavioral Therapy (CBT) is recommended as first-line therapy for chronic insomnia by the American Academy of Sleep Medicine (AASM),² the European Sleep Research Society,⁴ and the Department of Veteran Affairs/Department of Defense (VA/DoD)⁵ based on high-quality evidence. Other treatments (including medications) may have benefit if CBT is ineffective or inaccessible.

Cognitive Behavioral Therapy

Evidence supports efficacy of both brief CBT interventions and longer therapy.⁴ Not all "talk therapy" is CBT. CBT is structured and goal-driven to reduce symptoms and improve functional status. It often involves homework for the patient.

CBT-I (CBT for insomnia) is typically offered over multiple sessions. Cognitive components of CBT-I attempt to address maladaptive thoughts, beliefs, and expectations about sleep.⁵ Behavioral components address sleep habits and can include sleep restriction therapy, stimulus control, relaxation therapy, and sleep hygiene education.⁵ For example, sleep restriction therapy involves establishing a sleep schedule that restricts the time spent in bed. The schedule is initially set based on the patient's

average total sleep time and is gradually modified to allow longer a sleep time when sleep efficiency improves. CBT-I has been shown to improve insomnia severity and sleep efficiency.⁵ There is also evidence that CBT-I can improve sleep quality, sleep latency (the time it takes to fall asleep), and time spent awake after initial sleep onset in adults with insomnia.⁵ Brief behavioral interventions, focusing on the behavioral components included in CBT-I, have also demonstrated efficacy for treatment of insomnia.⁵

Access to nonpharmacological treatments such as CBT may be a significant barrier for many patients. Currently, there are not enough qualified providers to meet the need for services in Oregon, and it may be especially difficult for patients to find providers with specialized training in both CBT and sleep medicine. Additionally, patients may have to travel significant distances to get care, or be unable to commit to the time required for CBT (e.g., scheduling time off work for visits). Telehealth services may help expand treatment options, particularly for people in rural areas, but the evidence supporting this provider-directed telemedicine or self-directed internet programs is limited. In a 2019 systematic review of therapy for insomnia, the VA/DoD found insufficient evidence to recommend for or against internet-based CBT-I as an alternative to face-to-face CBT-I.⁵ There is some evidence that internet-based CBT-I is more effective than no treatment, but the magnitude of benefit is unclear.⁵ Evidence was limited by inconsistency, imprecision and indirectness.⁵ Since the coronavirus pandemic, telehealth services have become more common, especially for behavioral health conditions.⁶ A 2023 systematic review evaluated telehealth services during the COVID-19 pandemic.⁶ A wide range of populations, outcomes, and conditions were identified comparing telehealth to in-person care which limits ability to make any general statements about differences in treatment delivery. Overall, authors concluded that telehealth may be comparable to in-person care when evaluating outcomes related to follow-up visits and patient-reported clinical outcomes.⁶ They identified mixed results for healthcare utilization outcomes, and highlighted the need to develop best practices around telehealth delivery for various conditions, patient populations, and treatment settings.⁶

If patients are unable to access CBT-I, a variety of other options may provide benefit for insomnia symptoms, though the evidence supporting these therapies in treatment of insomnia is limited. These options can include lifestyle changes, relaxation techniques, sleep hygiene, self-directed

psychoeducation, other types of psychotherapy, and medicine.

Sleep hygiene involves education on healthy lifestyle practices to improve sleep.⁷ The American Academy of Sleep Medicine and VA/DoD recommend that all patients with insomnia follow principles of good sleep hygiene in combination with other treatments since there is insufficient evidence that these therapies are effective alone.^{1,5} Sleep hygiene education is typically incorporated into CBT-I. Common practices include:⁷

- Modify sleep environment so that it is conducive to sleep (e.g., cool temperatures, separating sleep and work environments).
- Keep a regular sleep schedule 7 nights a week; avoid naps during the day.
- Avoid going to bed until drowsy, do not watching the clock, get out of bed if not asleep within 15-20 minutes, and return to bed only when drowsy.
- Avoid substances that interfere with sleep (such as caffeine, nicotine, alcohol) before bedtime.
- Avoid electronic devices before bedtime. Light from screens can promote wakefulness and make it more difficult to sleep.
- Exercise regularly (at least 6 hours before sleep).

Sedative Drugs

Efficacy

When compared to CBT-I, medications were less effective for treating long-term insomnia symptoms (e.g., greater than 4 weeks) based on low-quality evidence.⁵ Most studies have only evaluated short-term use of insomnia drugs, and there is a lack of clear long-term safety data. A 2019 systematic literature review from the VA/DoD found insufficient evidence that use of diphenhydramine, ramelteon, suvorexant, or antipsychotics improve insomnia symptoms. Additionally, they suggest against use of melatonin, antipsychotics, trazodone, diphenhydramine, or benzodiazepines because risks of therapy likely outweigh any potential benefits. If drugs are offered for insomnia, they suggest the use of low-dose (3 or 6 mg) doxepin or non-benzodiazepine receptor agonists such as zolpidem, zaleplon or eszopiclone. There is a lack of clear efficacy or safety data for most sedatives beyond 2 to 4 weeks.

Table 1. VA/DoD recommendations for insomnia drug therapy⁵

Suggested for Short-term Use	Insufficient Evidence For or Against	Not Recommended
doxepin (3 or 6 mg)	ramelteon	antipsychotics
eszopiclone	suvorexant	benzodiazepines
zaleplon		chamomile*
zolpidem		diphenhydramine*
		kava*
		melatonin*
		trazodone
		valerian*

*Available in over-the-counter (OTC) formulations

There was low-quality evidence that melatonin was no different from placebo in adults with insomnia, and many clinical studies

evaluating diphenhydramine did not differentiate from placebo.⁵ Tolerance to sedating effects of diphenhydramine have also been observed even after 3 to 4 days of continuous use, limiting efficacy for insomnia.⁵ Similarly, trazodone, benzodiazepines, and antipsychotics are associated with serious long-term adverse effects and their efficacy for treatment of insomnia symptoms is limited. A systematic review found moderate-quality evidence that trazodone improved subjective sleep quality, but low-quality evidence of no improvement in other efficacy outcomes (such as total sleep time or sleep latency).⁵ Quetiapine, though commonly prescribed at low doses, has not been studied for insomnia, and evidence is limited to a few case studies and case series.⁵ Therefore, quetiapine is not recommended because unknown benefits in insomnia do not outweigh risk for known adverse effects (such as dyskinesias, metabolic changes, anticholinergic and ophthalmic effects).

Safety

Drug-drug and drug-disease interactions are common with sedatives. Before initiating therapy, providers should evaluate sleep history and assess for contraindications. Because some sedatives are available as over-the-counter (OTC) drugs, routine assessment for drug interactions and patient education regarding adverse effects is important. Over-the-counter formulations undergo less regulation by the FDA and may have varying levels of active ingredient or additional ingredients. One study evaluating content of 31 melatonin products identified that the amount of melatonin ranged from -83% to 465% of the labelled content and varied across lots, manufacturers, and product types.⁸ Varying levels of serotonin were identified in 8 (26%) of the products.⁸

Common adverse effects associated with all sedative medications include dizziness, daytime drowsiness, and somnolence. Risk for daytime impairment may be higher in women or elderly who metabolize and eliminate sedative medications more slowly from the body.⁹ The Food and Drug Administration (FDA) warns that high levels of a sedative in the bloodstream can result in impairment even if patients feel fully awake.⁹

Other notable safety concerns include anticholinergic adverse effects (including confusion, palpitations, dry mouth, and cognitive impairment) associated with antihistamines like doxepin and diphenhydramine. FDA labeling for all prescription sedative drugs (i.e., benzodiazepines, non-benzodiazepine receptor agonists, melatonin receptor agonists and orexin receptor antagonists) includes risk for rare but serious adverse effects like worsening depression and suicidal ideation, abnormal behavior changes (e.g., agitation, amnesia, hallucinations), and complex sleep behaviors (e.g., sleep driving). Additionally, parasomnias

(such as sleep paralysis) have been reported with suvorexant and daridorexant. All sedating drugs may increase risk of respiratory depression in patients with pulmonary conditions such as sleep apnea or obesity-related hypoventilation.⁵ Risk of overdose may be increased when sedatives (particularly benzodiazepines) are combined with opioids, alcohol or other medications. Adverse effects of sedatives may exacerbate symptoms in people who have cognitive disorders, are elderly, or are already at risk of falls.⁵ Evidence from observational studies indicates long-term sedative use increases risk of fractures and dementia.^{5,10,11} The risk of fracture may depend on the length of time people used the drugs, with new users of these drugs at greatest risk of hip fracture.^{10,11}

All sedative-hypnotics can be associated with physical dependence, but dependence is typically most pronounced with benzodiazepines. When discontinuing treatment, a taper plan is usually recommended to minimize withdrawal symptoms and facilitate discontinuation after routine, long-term use. The Oregon Health Authority Mental Health Clinical Advisory Group (MHCAG) has published guidance and best practices on how to approach a benzodiazepine taper.¹² Taper schedules should be individualized based on patient circumstances, diagnoses, dose, and length of benzodiazepine use. Many patients may benefit in switching, or cross-tapering, to a longer-acting benzodiazepine like diazepam before reducing their total benzodiazepine dose.¹²

Oregon Medicaid Policy Updates

Melatonin coverage in children

In October 2021, the Oregon fee-for-service (FFS) Open Card coverage policy was expanded to cover melatonin in children. This policy change was made based on a review of available low-quality evidence which demonstrated that melatonin may improve sleep latency and sleep duration in children, but evidence is insufficient to draw conclusions on improvements in nighttime awakenings or functional outcomes, or on increased frequency of some adverse events (e.g., dizziness, daytime drowsiness, and bed-wetting).¹³ Doses studied ranged from 2 to 12 mg.¹³ The American Academy of Sleep medicine suggests that doses of 3 to 5 mg may be effective in children.¹⁴ Children with autism or other neurodevelopmental disorders had the largest improvement in sleep outcomes with melatonin nightly.¹³ However, evidence was generally limited to short-term studies (<6 months), and the long-term safety of melatonin use is less clear.^{15,16} Because of the unknown long-term safety concerns related to use of a hormone in children, non-pharmacologic behavioral therapy remains a first-line treatment option, and melatonin is usually recommended at the lowest effective dose with frequent re-assessment to evaluate change in symptoms.¹⁶ Melatonin is not currently covered for adults enrolled in FFS Medicaid due to the limited evidence of benefit in this population.

Cognitive behavioral therapy (CBT) coverage

Beginning in January 2024, the Health Evidence Review Commission (HERC) adopted a new guideline which addresses treatments for insomnia. This new policy provides coverage of CBT for insomnia. Historically, both medical and pharmacological treatments for insomnia have been unfunded and had very limited coverage. Beginning January 1, 2024, providers can bill the Oregon Health Plan for CBT visits related to insomnia.

Coverage of provider-directed telemedicine varies based on the insurance carrier. When referring patients for internet-based programs, providers might consider directing patients toward the [evidence-based app](#) developed by the VA/DoD for management of insomnia.

Limits for sedatives

As part of coverage changes for insomnia starting January 2024, HERC has also recommended additional limits for sedative-hypnotic use for insomnia. Consistent with current guidelines, use of sedative-hypnotics for insomnia is recommended for short-term therapy only. Coverage is limited to one month per year with additional therapy requiring documentation that treatment benefits outweigh risks. The specific duration of treatment was recommended due to concerns with long-term risks of sedative hypnotics and increasing risk of dependence with longer-term use.

Conclusion

CBT-I is recommended as first-line treatment for chronic insomnia symptoms. Drugs are only recommended for short-term treatment of insomnia due to their limited evidence of benefit and serious long-term adverse effects. Oregon Medicaid recently updated their coverage for CBT-I. Initial treatment of sedative-hypnotics for insomnia is limited to one month.

Resources

- [MHCAG: general recommendations for CBT](#)
- [MHCAG: How to approach a benzodiazepine taper](#)
- [Prior Authorization Criteria](#) for FFS Medicaid patients
- [CBT-I Coach](#), a mobile app from the VA/DOD for

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