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Prior Authorization Criteria Update: Sedatives

Plain Language Summary:

- How does new guidance affect the current Medicaid Open Card policy?
- Guidance was recently published from the Oregon Health Evidence Review Commission (HERC). They recommend coverage of cognitive behavioral therapy for sleep disorders starting January 2023. This is supported by current recommendations from the American Academy of Sleep Medicine and European Sleep Research Society.
- The American Academy of Sleep Medicine and the European Sleep Research Society recommend cognitive behavioral therapy (CBT) for sleep disorders:
    - that make it difficult to fall asleep or stay asleep *and*
    - where lack of sleep creates difficulty doing activities during the day.
- Providers can prescribe medicines for sleep disorders when cognitive behavioral therapy does not improve patient sleep.
- The Oregon Health Evidence Review Commission recommended that Medicaid cover sedatives for only 30 days because of side effects with longer use.
    - Side effects include increased risk of memory problems, falls, broken bones, inability to sleep without use of these medicines, and daytime sleepiness.
    - Risk of side effects may increase as people get older, particularly if over 65 years of age and when combined with other medicines that have similar side effects.
- Providers must explain to the Oregon Health Authority why someone needs a sedative before Medicaid will pay for it. This process is called prior authorization.
- Medicaid Open Card will pay for melatonin without prior authorization when prescribed for children. Melatonin is not covered for adults.
- The Drug Use Research Management program recommends policy updates to match HERC guidance.

Purpose of Update:

Beginning on January 1, 2023, the Health Evidence Review Commission (HERC) adopted a new guideline which addresses treatments for insomnia. This new policy pairs cognitive behavioral therapy for treatment of insomnia on a funded line and recommends limitation of sedative-hypnotics to short-term use only (1 month per year) in patients who are currently participating in or have previously failed to have benefit with cognitive behavioral therapy (CBT). 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. Previously, both medical and pharmacological treatments for insomnia had been unfunded.

Evidence for this class was last reviewed by the Pharmacy and Therapeutics Committee in August 2022. Cognitive Behavioral Therapy (CBT) is recommended as first-line therapy for chronic insomnia by both the American Academy of Sleep Medicine[1] and the European Sleep Research Society[2] based on high-quality evidence. A sedative can be offered if CBT is not effective or not available.[1,2] Evidence supports efficacy of both brief CBT interventions and longer therapy.[2] Orexin receptor antagonists (suvorexant), benzodiazepines (triazolam and temazepam only), benzodiazepine receptor agonists (eszopiclone, zaleplon, zolpidem), doxepin, and ramelteon all have weak recommendations to treat sleep onset and/or sleep maintenance insomnia based on low-quality evidence.[1] However,

long-term treatment of chronic insomnia with a sedative (≥12 weeks) is not recommended because of lack of evidence and possible adverse effects based on low-quality evidence.[2] FDA labeling for most sedative drugs indicated for insomnia recommends re-evaluation of comorbid diagnoses which could be contributing to symptoms if insomnia persists for more than 7-10 days of treatment. Trazodone, quetiapine, and diphenhydramine are not recommended due to adverse effects and lack of efficacy, and there is insufficient evidence for use of melatonin in adults.[1]

Common adverse effects associated with sedative medications include dizziness, daytime drowsiness, and somnolence. Evidence from observational studies indicates long-term sedative use may be associated with increased risk of fractures and dementia. 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.[3] FDA labeling for non-benzodiazepine sedatives includes warnings for risk of rare but serious adverse effects including daytime memory and psychomotor impairment, abnormal thinking and behavior changes, parasomnias (such as sleep paralysis), complex behaviors (such as sleep driving), depression, and suicidal thoughts and actions. Risk for daytime impairment may be higher in women or elderly who metabolize and eliminate sedative medications more slowly from the body.[4] The FDA warns that high levels of a sedative in the bloodstream can result in impairment even if patients feel fully awake.[4] Benzodiazepine sedatives are also associated with physical dependence and a taper plan is usually recommended to minimize withdrawal symptoms and facilitate discontinuation after routine, long-term use. Provider resources and best practices for benzodiazepine tapers were recently published by the Oregon Health Authority Mental Health Clinical Advisory Group (MHCAG).[5] Taper schedules 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.[5]

Recommendation:

- Update prior authorization criteria to limit sedative use to 30 days and encourage use of cognitive behavioral therapy for insomnia.

References:

1. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(2):307-349.
2. Riemann D, Baglioni C, Bassetti C, et al. European guideline for the diagnosis and treatment of insomnia. J Sleep Res. 2017;26(6):675-700.
3. Oregon State University Drug Use Research and Management Program. Drug Class Update with New Drug Evaluation: Sedatives. December 2020. https://www.orpdl.org/durm/meetings/meetingdocs/2020_12_03/archives/2020_12_03_Sedatives_ClassUpdate.pdf Accessed April 12, 2022.
4. Mental Health Problems in People with Learning Disabilities: Prevention, Assessment and Management. NICE Guideline, No. 54. National Guideline Alliance (UK). London: National Institute for Health and Care Excellence (UK); 2016 Sep. https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0089546/. Accessed 10/27/17.
5. Oregon Health Authority. Mental Health Clinical Advisory Group. How to approach a benzodiazepine taper. May 2022. Available online at https://www.oregon.gov/oha/HPA/DSI-Pharmacy/MHCAGDocs/Tapering-Benzodiazepines.pdf. Accessed June 15, 2022.

Appendix 1. Proposed Safety Edits

Sedatives

Goals:

- Restrict use of sedatives to OHP-funded conditions. Long-term treatment of insomnia is not funded.
- Encourage use of cognitive behavioral therapy for insomnia.

- Prevent concomitant use of sedatives, including concomitant use with benzodiazepines or opioids.
- Limit daily zolpidem dose to the maximum recommended daily dose by the FDA.
- Permit use of melatonin in children and adolescents 18 years of age or younger.

Length of Authorization:

- Up to 12 months or lifetime (criteria-specific)

Requires PA:

- All sedatives (e.g., sedative hypnotics, hypnotics-melatonin agonists) except melatonin in children and adolescents. Melatonin is not covered for adults over 18 years of age.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Zolpidem Daily Quantity Limits

Generic	Brand	Max Daily Dose
Zolpidem	Ambien	10 mg
Zolpidem ER	Ambien CR	12.5 mg

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for melatonin in an adult over 18 years of age?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #3
3. Is the request for zolpidem at a higher dose than listed in the quantity limit chart?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #4

Approval Criteria		
4. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product? Message: Preferred products are evidence-based and reviewed for comparative effectiveness and safety by the P&T Committee.	**Yes:** Inform prescriber of preferred alternatives in class. Go to #5	**No:** Go to #5
5. Is the patient being treated under palliative care services (ICD10 Z51.5) with a life-threatening illness or severe advanced illness expected to progress toward dying?	**Yes:** Approve for lifetime.	**No:** Go to #6
6. Has the patient been treated with a different non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days?	**Yes:** Go to #7	**No:** Go to #9
7. Is this a switch in sedative therapy due to intolerance, allergy or ineffectiveness?	**Yes:** Go to #9 Document reason for switch.	**No:** Go to #8
8. Is concurrent sedative therapy part of a plan to switch and taper off a long-acting benzodiazepine (such as diazepam, clonazepam, or chlordiazepoxide) AND has the provider included a detailed strategy to taper? Note: a documented taper strategy should include planned dose reductions and length of time between each dose modification for at least the next few weeks. It should also include a documented follow-up plan to monitor progress and manage withdrawal symptoms (regular check-ins are essential for a successful taper). Triazolam may be discontinued without a taper in most cases (2-hour half-life prevents physical dependence).	**Yes:** Approve duplicate benzodiazepine therapy for the duration specified in the taper plan (not to exceed 6 months).	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
9. Does the patient have a diagnosis of insomnia with obstructive sleep apnea?	**Yes:** Go to #10	**No:** Go to #11
10. Is the patient on CPAP?	**Yes:** Go to # 11	**No:** Pass to RPh. Deny; medical appropriateness. Sedative/hypnotics are contraindicated due to depressant effect.
11. Is the request for treatment of insomnia?	**Yes:** Go to #12	**No:** Go to #13
12. Is the patient currently engaged in cognitive behavioral therapy focused on insomnia treatment, failed to have benefit in symptoms after 5-6 CBT interventions, or have inability to access CBT focused on treatment of insomnia?	**First request:** Sedative treatment can be approved for 30 days. Long-term treatment must document that benefits outweigh risks. **Subsequent request:** Go to **Renewal Criteria**	**No:** Pass to RPh. Deny; medical appropriateness.
13. RPh only: Is diagnosis being treated a funded condition and is there medical evidence of benefit for the prescribed sedative?	**Funded:** Document supporting literature and approve 30 days with subsequent approvals dependent on follow-up and documented response.	**Not Funded:** Deny; not funded by OHP.

Renewal Criteria		
1. Is the request for a slow taper plan?	**Yes:** Approve for duration of taper (not to exceed 3 months). Subsequent requests should document progress toward discontinuation,	**No:** Go to #2

Renewal Criteria		
2. Is there documentation that benefits of ongoing benefits (hospitalizations, function, quality of life), outweigh risks (memory problems, dementia, cognitive impairment, daytime sedation, falls, fractures, dependence, and reduced long-term efficacy)?	**Yes:** Approve for 3 months	**No:** Pass to RPh. Deny; medical appropriateness.

P&T/DUR Review: *12/22 (SS); 8/22; 12/20; 7/18; 3/17; 11/14, 3/14, 5/06, 2/06, 11/05, 9/05, 2/04, 2/02, 9/01*
Implementation: *1/1/23; 10/1/22; 1/1/21; 8/15/18; 1/1/15, 7/1/14; 1/1/07, 7/1/06, 11/15/05*