Sedatives

Goals:

- Restrict use of sedatives to OHP-funded conditions, with individual review for individuals covered under the EPSDT program. Long-term treatment of insomnia with sedatives 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
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

Approval Criteria		
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 5 years	**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.
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

Approval Criteria		
12. Is the patient currently engaged in cognitive behavioral therapy focused on insomnia treatment (CBT-I), failed to have benefit in symptoms after 5-6 CBT interventions, OR have inability to access CBT-I?	**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?	**Yes:** Document supporting literature and approve 30 days with subsequent approvals dependent on follow-up and documented response.	**No:** For current age ≥ 21 years: Deny; not funded by OHP. For current age < 21 years: Go to #14
14. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?	**Yes:** Go to #15 Document baseline severity	**No:** Pass to RPh. Deny; medical necessity.
15. Is the request for a melatonin agonist (e.g., melatonin, ramelteon, tasimelteon) for treatment of one of the following circadian rhythm sleep-wake disorders: • People with delayed sleep-wake phase disorder • Adults with non-24 hour sleep-wake disorder • Children and adolescents with neurologic disorders and irregular sleep-wake rhythm disorder?	**Yes:** Approve for approve 30 days with subsequent approvals dependent on follow-up and documented response.	**No:** Pass to RPh. Deny; medical appropriateness.

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 the request for treatment of an unfunded condition previously approved by FFS?	**Yes:** For current age < 21 years: Go to #3 For current age ≥21 years: Pass to RPh. Deny; not funded by OHP	**No:** Go to #4
3. Is there documentation of improvement (e.g., of symptoms, function, quality of life, etc) since treatment was started?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.
4. Is there documentation based on medical records that the patient and provider have discussed whether benefits of ongoing therapy (hospitalizations, function, quality of life) continue to 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: *1/1/24; 10/1/22; 1/1/21; 8/15/18; 1/1/15, 7/1/14; 1/1/07, 7/1/06, 11/15/05*