Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCCNS059.0825	**MISCELLANEOUS PRODUCTS** **INSOMNIA AGENTS** See Table 1 for applicable medications
Effective Date: 11/1/2025	**Review/Revised Date**: 01/21, 06/21, 08/22, 07/23, 06/24, 07/25 (KN)
Original Effective Date: 01/21	**P&T Committee Meeting Date**: : 10/20, 02/21, 08/21, 10/22, 08/23, 08/24, 08/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Medicaid

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services when all applicable indication-specific criteria below are met or if the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit applies.

For Medicaid: Insomnia is considered "below the line." Therefore, coverage is dependent on whether the insomnia adversely affects, or is secondary to, a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

REQUIRED MEDICAL INFORMATION:
Initial Authorization:
1. Patient is being treated under palliative care services with a life-threatening illness or severe advanced illness expected to progress towards dying, OR
2. Patient is being treated for a funded condition that cannot be controlled with standard treatments and meets all the following:
    a. Patient is currently being treated for a funded co-morbid condition as indicated by one of the following:

i. Obstructive sleep apnea: CPAP
ii. Depression, anxiety, panic disorder, bipolar disorder: antidepressant, antipsychotic, or other appropriate mental health drug
iii. Other funded condition which is being exacerbated by insomnia, for which there is evidence of medical benefit of sedatives, and is not currently controlled by standard treatments

b. Patient has not been treated with another non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days. If patient has been treated with a sedative in past 30 days, this criteria may be waived if this is a switch in sedative therapy due to intolerance, allergy, or ineffectiveness of prior sedative and notes clearly indicate that the other sedative has been discontinued
c. Patient has had a documented trial of Cognitive Behavior Therapy (CBT) which must include education on sleep hygiene improvements
d. For non-preferred drugs: Trial and failure, contraindication, or intolerance to generic ramelteon AND generic zolpidem. Exception: melatonin will not be covered for adult patients 18 years of age and older.

Reauthorization:
Patient has a need for continued treatment with a sedative, meeting one of the following:

1. Patient is being treated under palliative care services with a life-threatening illness or severe advanced illness expected to progress towards dying, OR
2. Patient is being treated for a funded condition that cannot be controlled with standard treatments and meets all the following:
    a. Patient is currently being treated for a funded co-morbid condition as indicated by one of the following:
        i. Obstructive sleep apnea: CPAP
        ii. Depression, anxiety, panic disorder, bipolar disorder: antidepressant, antipsychotic, or other appropriate mental health drug
        iii. Other funded condition which is being exacerbated by insomnia, for which there is evidence of medical benefit of sedatives, and is not currently controlled by standard treatments
    b. Patient has had a positive response to therapy without side effects and noted improvement in the funded condition
    c. If patient is taking a non-benzodiazepine sedative, benzodiazepine, or opioid in combination with the requested sedative the following must be met:
        i. Rationale must be provided addressing need for continuing sedative therapy despite potential risks, AND

ii. Documentation that the requested sedative, non-benzodiazepine sedative, benzodiazepine, or opioid has been titrated down from the initial authorization OR documentation of a specific tapering plan OR medical rationale for not attempting a taper at this time

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Initial and reauthorization will be approved for up to one year

QUANTITY LIMIT:
See Table 2 for quantity limits

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Cognitive behavioral therapy (CBT) and pharmacotherapy are the main treatment options for chronic insomnia. While CBT is the preferred first-line treatment, it is not effective for all patients, and/or there may be limitations on access to care. Medications used to treat insomnia include those in the following classes: benzodiazepine receptor agonists (BZRAs, including benzodiazepines and nonbenzodiazepine BZRAs, or "z drugs"), sedating antidepressants, melatonin agonists, orexin receptor antagonists, and antipsychotics.

FDA APPROVED INDICATIONS:

- Ambien® (zolpidem) is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.
- Ambien CR® (zolpidem extended release) is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance (as measured by wake time after sleep onset).
- Belsomra® (suvorexant) is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
- Dayvigo® (lemborexant) is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.
- Intermezzo® (zolpidem sublingual) is indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep.
    - Limitation of Use: Not indicated for the treatment of middle-of-the night awakening when the patient has fewer than four hours of bedtime remaining before the planned time of waking
- Lunesta® (eszopiclone) is indicated for the treatment of insomnia.
- Quviviq® (daridorexant) indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance
- Restoril® (temazepam) is indicated for the short-term treatment of insomnia.
- Rozerem® (ramelteon) is indicated for the treatment of insomnia characterized by difficulty with sleep onset.
- Silenor® (doxepin) is indicated for the treatment of insomnia characterized by difficulty with sleep maintenance.
- Triazolam is indicated for the short-term treatment of insomnia.
- Zaleplon is indicated for the short-term treatment of insomnia.

POSITION STATEMENT:
Oregon Health Authority (OHA) only covers medications used to treat conditions on the prioritized list of covered services. Treatment of uncomplicated insomnia is not funded; however, insomnia contributing to a covered co-morbid condition may be funded.

CBT for insomnia (CBT-I) is preferred as first-line therapy for chronic insomnia. CBT-I is an approach to chronic insomnia that addresses common thoughts and behaviors that interfere with optimal sleep.
The behavioral components of CBT-I include:
- Establishment of a stable bedtime and wake time seven days per week
- Reduction in time in bed to approximate the total hours of estimated sleep (sleep restriction)

- Encouragement to use the bed only for sleep and sex; try to sleep only when sleepy; and get out of bed if anxiety occurs while unable to sleep (stimulus control)
- Sleep hygiene, which includes avoidance of substances that interfere with sleep, avoidance of naps to maximize sleep drive, and optimization of the comfort of the sleep environment (table 3)

The cognitive approaches of CBT-I address:
- Anxious and catastrophic thoughts that are associated with sleeplessness
- Inappropriate expectations about hours of sleep
- Misattributions regarding the effects of sleeplessness
- Relaxation through progressive muscle relaxation, mindfulness, and meditation

The American Academy of Sleep Medicine (AASM) practice guideline suggests choosing pharmacological therapy based on the type of insomnia (i.e., sleep onset or sleep maintenance) and the duration of effect:
- Sleep onset insomnia: a short-acting medication is a reasonable option for an initial trial of pharmacologic therapy. Short-acting medications may improve the insomnia with less residual somnolence the following morning. Examples of short-acting medications (duration of effect ≤8 hours) include zaleplon, zolpidem, triazolam, and ramelteon.
- Sleep maintenance insomnia: a longer-acting medication is a preferred option for an initial trial of pharmacologic therapy. Examples of longer-acting medications include zolpidem extended release, eszopiclone, temazepam, low dose doxepin, and suvorexant. Longer-acting medications may increase the risk for hangover sedation.

A systematic review was completed in 2015 by the Agency for Healthcare Research and Quality (AHRQ) to assess the efficacy, comparative effectiveness, and adverse effects of various treatment strategies for insomnia in adults. This review noted the following conclusions: “CBT-I or medical therapy with eszopiclone, zolpidem, and suvorexant improve global and sleep outcomes for insomnia disorder. Clinical significance, applicability, comparative effectiveness, and long-term efficacy, especially among older adults, are less well known. Effect sizes vary, and a large placebo response is sometimes observed. Observational studies suggest an association of hypnotics with infrequent but serious harms. FDA labels provide specific warnings and precautions for drugs approved for insomnia.”

Early and Periodic Screening Diagnostic and Treatment (EPSDT) Review

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit includes comprehensive preventative health care services for Medicaid members until they turn age 21 and for members with qualifying special health care needs

(Youth with Special Healthcare Needs (YSHCN)) as they turn 21. This benefit applies when a condition is determined to impact the ability to grow, develop or participate in school and the applicable criteria above are met.

Table 1: Sedatives covered by this policy

Preferred Sedatives	Non-Preferred Sedatives
Melatonin (covered for children 18 years of age and younger)	Ambien® and Ambien CR®
Ramelteon (generic Rozerem®)	Belsomra®
Zolpidem immediate- release (generic Ambien®)	Dayvigo®
	Doxepin (generic Silenor®)
	Eszopiclone (generic Lunesta®)
	Lunesta®
	Restoril™
	Rozerem®
	Quviviq®
	Silenor®
	Temazepam (generic Restoril™)
	Triazolam (generic Halcion®)
	Zaleplon (generic Sonata®)
	Zolpidem extended-release
	Zolpidem sublingual (generic Intermezzo®)

Table 2: Quantity Limit

Drug	Quantity Limit
Belsomra® (suvorexant)	1 tablet per day
Dayvigo® (lemborexant)	1 tablet per day
Eszopiclone	1 tablet per day
Quviviq® (daridorexant)	1 tablet per day
Rozerem® (ramelteon)	1 tablet per day
Silenor® (doxepin)	1 tablet per day
Temazepam	1 capsule per day
Triazolam	0.125mg: 1 tablet per day 0.25mg: 2 tablets per day
Zaleplon	2 capsules per day
Zolpidem extended-release	1 tablet per day
Zolpidem immediate-release	5mg: 2 tablets per day 10mg: 1 tablet per day
Zolpidem sublingual	1 tablet per day

REFERENCE/RESOURCES:

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