Effective Date..... 12/15/2024
Coverage Policy Number IP0023

Sedative Hypnotic Medications

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following sedative hypnotic products:

- Ambien® (zolpidem tablets)
- Ambien CR® (zolpidem extended-release tablets)
- Belsomra® (suvorexant)
- Edluar® (zolpidem sublingual tablets)
- Intermezzo® (zolpidem sublingual tablets)
- Quviviq™ (daridorexant)
- Restoril® (temazepam)
- zolpidem tartrate 7.5 mg capsules
- Zolpimist® (zolpidem oral spray)

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Product	Criteria
Ambien (zolpidem immediate-release tablets)	**Ambien** is considered medically necessary when the individual meets **ALL** of the following: **Chronic Insomnia**. Individual meets **BOTH** of the following: A. **ONE** of the following: i. Has a cancer diagnosis ii. **ALL** of the following: 1. Age 18 years or older 2. Has tried at least one form of behavioral therapy for insomnia (for example, relaxation training, stimulus control therapy, sleep restriction therapy) 3. Not currently taking prescription stimulants (for example, methylphenidate, amphetamine products) 4. Underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia have been evaluated and are currently being addressed, according to the health care professional. B. Documentation of **BOTH** of the following: i. Has tried **zolpidem** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. ii. Failure, contraindication, or intolerance to **TWO** of the following: 1. doxepin (Silenor generic) 2. eszopiclone (Lunesta generic) 3. zaleplon (Sonata generic)
Ambien CR (zolpidem extended-release tablets)	**Ambien CR** is considered medically necessary when the individual meets **ALL** of the following: **Chronic Insomnia**. Individual meets **BOTH** of the following: A. **ONE** of the following: i. Has a cancer diagnosis ii. **ALL** of the following: 1. Age 18 years or older 2. Has tried at least one form of behavioral therapy for insomnia (for example, relaxation training, stimulus control therapy, sleep restriction therapy) 3. Not currently taking prescription stimulants (for example, methylphenidate, amphetamine products) 4. Underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia have been evaluated and are currently being addressed, according to the health care professional. B. Documentation of **BOTH** of the following: i. Has tried **zolpidem** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.

Product	Criteria
	ii. Failure, contraindication, or intolerance to **TWO** of the following: 1. doxepin (Silenor generic) 2. eszopiclone (Lunesta generic) 3. zaleplon (Sonata generic)
Belsomra (suvorexant)	**Belsomra** is considered medically necessary when the individual meets **ALL** of the following: **Chronic Insomnia**. Individual meets **BOTH** of the following: A. **ONE** of the following: i. Has a cancer diagnosis ii. **ALL** of the following: 1. Age 18 years or older 2. Has tried at least one form of behavioral therapy for insomnia (for example, relaxation training, stimulus control therapy, sleep restriction therapy) 3. Not currently taking prescription stimulants (for example, methylphenidate, amphetamine products) 4. Underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia have been evaluated and are currently being addressed, according to the health care professional. B. Documentation of **ONE** of the following: i. 18 to 64 years of age and failure, contraindication, or intolerance to **THREE** of the following: 1. Dayvigo 2. doxepin (Silenor generic) 3. eszopiclone (Lunesta generic) 4. ramelteon (Rozerem generic) 5. zaleplon (Sonata generic) 6. zolpidem (Ambien generic) ii. 65 years of age and older and failure, contraindication, or intolerance to **ONE** of the following: 1. Dayvigo 2. doxepin (Silenor generic) 3. ramelteon (Rozerem generic)
Edluar (zolpidem sublingual tablets)	**Edluar** is considered medically necessary when the individual meets **ALL** of the following: **Chronic Insomnia**. Individual meets **BOTH** of the following: A. **ONE** of the following: i. Has a cancer diagnosis ii. **ALL** of the following: 1. Age 18 years or older 2. Has tried at least one form of behavioral therapy for insomnia (for example, relaxation training, stimulus control therapy, sleep restriction therapy) 3. Not currently taking prescription stimulants (for example, methylphenidate, amphetamine products)

Product	Criteria
	4. Underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia have been evaluated and are currently being addressed, according to the health care professional. B. Documentation of **ONE** of the following: i. Cannot swallow of has difficulty swallowing solid oral dosage forms ii. Failure, contraindication, or intolerance to **THREE** of the following: 1. doxepin (Silenor generic) 2. eszopiclone (Lunesta generic) 3. zaleplon (Sonata generic) 4. zolpidem (Ambien generic)
Intermezzo (zolpidem sublingual tablets)	**Intermezzo** is considered medically necessary when the individual meets **ALL** of the following: **Chronic Insomnia**. Individual meets **BOTH** of the following: A. **ONE** of the following: i. Has a cancer diagnosis ii. **ALL** of the following: 1. Age 18 years or older 2. Has tried at least one form of behavioral therapy for insomnia (for example, relaxation training, stimulus control therapy, sleep restriction therapy) 3. Not currently taking prescription stimulants (for example, methylphenidate, amphetamine products) 4. Underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia have been evaluated and are currently being addressed, according to the health care professional. B. Documentation of **BOTH** of the following: i. Has tried **zolpidem sublingual tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. ii. Failure, contraindication, or intolerance to **TWO** of the following: 1. doxepin (Silenor generic) 2. eszopiclone (Lunesta generic) 3. zaleplon (Sonata generic)
Quviviq (daridorexant)	**Quviviq** is considered medically necessary when the individual meets **ALL** of the following: **Chronic Insomnia**. Individual meets **BOTH** of the following: A. **ONE** of the following: i. Has a cancer diagnosis ii. **ALL** of the following: 1. Age 18 years or older

Product	Criteria
	2. Has tried at least one form of behavioral therapy for insomnia (for example, relaxation training, stimulus control therapy, sleep restriction therapy) 3. Not currently taking prescription stimulants (for example, methylphenidate, amphetamine products) 4. Underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia have been evaluated and are currently being addressed, according to the health care professional. B. Documentation of **ONE** of the following: i. 18 to 64 years of age and failure, contraindication, or intolerance to **THREE** of the following: 1. Dayvigo 2. doxepin (Silenor generic) 3. eszopiclone (Lunesta generic) 4. ramelteon (Rozerem generic) 5. zaleplon (Sonata generic) 6. zolpidem (Ambien generic) ii. 65 years of age and older and failure, contraindication, or intolerance to **ONE** of the following: 1. Dayvigo 2. doxepin (Silenor generic) 3. ramelteon (Rozerem generic)
Restoril (temazepam)	**Restoril** is considered medically necessary when the individual meets **ALL** of the following: **Chronic Insomnia**. Individual meets **BOTH** of the following: A. **ONE** of the following: i. Has a cancer diagnosis ii. **ALL** of the following: 1. Age 18 years or older 2. Has tried at least one form of behavioral therapy for insomnia (for example, relaxation training, stimulus control therapy, sleep restriction therapy) 3. Not currently taking prescription stimulants (for example, methylphenidate, amphetamine products) 4. Underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia have been evaluated and are currently being addressed, according to the health care professional. B. Documentation of **BOTH** of the following: i. Has tried **temazepam** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction. ii. Failure, contraindication, or intolerance to **ONE** of the following: 1. doxepin (Silenor generic) 2. eszopiclone (Lunesta generic)

Product	Criteria
	3. zaleplon (Sonata generic) 4. zolpidem (Ambien generic)
Zolpidem Tartrate 7.5 mg oral capsules	**Zolpidem Tartrate 7.5 mg** is considered medically necessary when the individual meets **ALL** of the following: **Chronic Insomnia**. Individual meets **BOTH** of the following: A. **ONE** of the following: i. Has a cancer diagnosis ii. **ALL** of the following: 1. Age 18 years or older 2. Has tried at least one form of behavioral therapy for insomnia (for example, relaxation training, stimulus control therapy, sleep restriction therapy) 3. Not currently taking prescription stimulants (for example, methylphenidate, amphetamine products) 4. Underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia have been evaluated and are currently being addressed, according to the health care professional. B. Documentation of **BOTH** of the following: i. Failure, contraindication, or intolerance to generic zolpidem tartrate 5 mg or 10 mg tablet ii. Failure, contraindication, or intolerance to **TWO** of the following: 1. doxepin (Silenor generic) 2. eszopiclone (Lunesta generic) 3. zaleplon (Sonata generic)
Zolpimist (zolpidem oral spray)	**Zolpimist** is considered medically necessary when the individual meets **ALL** of the following: **Chronic Insomnia**. Individual meets **BOTH** of the following: A. **ONE** of the following: i. Has a cancer diagnosis ii. **ALL** of the following: 1. Age 18 years or older 2. Has tried at least one form of behavioral therapy for insomnia (for example, relaxation training, stimulus control therapy, sleep restriction therapy) 3. Not currently taking prescription stimulants (for example, methylphenidate, amphetamine products) 4. Underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia have been evaluated and are currently being addressed, according to the health care professional. C. Documentation of **ONE** of the following: i. Cannot swallow of has difficulty swallowing solid oral dosage forms

Product	Criteria
	ii. Failure, contraindication, or intolerance to **THREE** of the following: 1. doxepin (Silenor generic) 2. eszopiclone (Lunesta generic) 3. zaleplon (Sonata generic) 4. zolpidem (Ambien generic)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of sedative hypnotic medications are considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW
All of the medications included in this policy are indicated for the **treatment of insomnia**.[1-12]

Zolpidem immediate-release (IR) tablets and extended-release (ER) tablets, Edluar, Zolpimist, zaleplon, and the benzodiazepine sedative hypnotics are indicated for the short-term treatment of insomnia.[1-3,5,6,12] Zolpidem capsules are indicated for short-term treatment of transient insomnia in adults < 65 years of age.[20] Eszopiclone, doxepin (3 mg or 6 mg), and ramelteon are also indicated for the treatment of insomnia, but their product labeling does not specifically limit their use to short-term.[4,8,9] All of the agents in this category have been shown to decrease sleep latency. Zaleplon and ramelteon are specifically indicated for the treatment of insomnia characterized by difficulty with sleep onset.[3,8] Zolpidem IR, zolpidem ER, doxepin (3 mg or 6 mg), and eszopiclone have also been shown to improve sleep maintenance or increase the duration of sleep.[1,2,4,9] Belsomra, Dayvigo, and Quviviq are indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.[10-12] Zolpidem sublingual tablets are indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep.[7]

Eszopiclone, zaleplon, zolpidem IR (tablets and capsules), zolpidem ER, zolpidem sublingual tablets, Edluar, Zolpimist, and the benzodiazepine sedative hypnotics are all schedule IV controlled substances.[1-7,12,20] Belsomra, Dayvigo, and Quviviq are also schedule IV controlled substances.[10-12] Neither ramelteon nor doxepin (3 mg or 6 mg) are controlled substances.[8,9] Doxepin is also available generically as oral capsules (10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg) and oral solution (10 mg/mL).[13] These higher dose formulations are recommended for use in patients with depression and/or anxiety of varying etiologies.

Disease Overview

Insomnia is defined in the International Classification of Sleep Disorders, Third Edition, as a complaint of trouble initiating or maintaining sleep, resulting in daytime consequences (e.g., daytime fatigue, irritability, and decreased concentration) which is not attributable to environmental circumstances or inadequate opportunity for sleep.[14] Generally, transient insomnia lasts less than 1 week, short-term (acute) insomnia lasts up to 3 months, and chronic insomnia lasts more than 3 months at a frequency of at least three times per week.[14,15] Describing insomnia by timing (difficulty falling asleep [sleep onset insomnia], difficulty staying asleep or getting back to sleep after awakening [sleep maintenance insomnia], or disrupted or non-refreshing sleep and/or early morning awakening) can be useful in the diagnosis and help to distinguish among sleep disorders. Additionally, the pattern of sleep difficulty provides a basis to match a medication based on timing of onset and duration of effect.

Guidelines

The American Academy of Sleep Medicine (AASM) published a clinical guideline for the evaluation and management of chronic insomnia in adults (2008).[17] The primary treatment goals are to improve sleep quality and quantity and to improve insomnia-related daytime impairments. Initial approaches to treatment should include at least one behavioral intervention such as stimulus control therapy or relaxation therapy, or the combination of cognitive therapy, stimulus control therapy, sleep restriction therapy with or without relaxation therapy. Patients should be instructed to keep a regular schedule; have a healthy diet, regular daytime exercise, and a quiet sleep environment; and avoid napping, caffeine, other stimulants, nicotine, alcohol, excessive fluids, or stimulating activities before bedtime. Short-term hypnotic treatment should be supplemented with behavioral and cognitive therapies when possible. Chronic hypnotic medication may be indicated for long-term use in patients with severe or refractory insomnia or chronic comorbid illness. Whenever possible, patients should receive an adequate trial of cognitive behavioral treatment during long-term pharmacotherapy. Long-term prescribing should be accompanied by regular follow-up, ongoing assessment of effectiveness, monitoring for adverse events, and evaluation for new onset or exacerbation of existing comorbid disorders.

The AASM published an updated clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults (2017).[14] The recommendations are intended as a guide for choosing a specific pharmacological agent (vs. no treatment) for treatment of chronic insomnia in adults, when such treatment is indicated. Each of the recommendations listed is weak, meaning it reflects a lower degree of certainty in the outcome and appropriateness of the patient care strategy for all patients but should not be construed as an indication of ineffectiveness. The guideline suggests that clinicians can use Belsomra as a treatment for sleep maintenance insomnia; eszopiclone can be used as a treatment for sleep onset and sleep maintenance insomnia; zaleplon can be used as a treatment for sleep onset insomnia; zolpidem can be used as a treatment for sleep onset and sleep maintenance insomnia; triazolam can be used as a treatment for sleep onset insomnia; temazepam can be used as a treatment for sleep onset and sleep maintenance insomnia; ramelteon can be used as a treatment for sleep onset insomnia; and doxepin (3 mg or 6 mg) can be used as a treatment for sleep maintenance insomnia. The guideline suggested that clinicians not use trazodone, tiagabine, diphenhydramine, melatonin, tryptophan, or valerian as a treatment for sleep onset or sleep maintenance insomnia. The authors note that cognitive behavioral therapy for insomnia (CBT-I) is a standard of care for this condition; however, the AASM guideline does not address the relative benefits of CBT-I vs. pharmacotherapy.

The American College of Physicians (ACP) developed a guideline on the management of chronic insomnia disorder in adults (2016).[18,19] The guideline is consistent with the AASM guidelines on chronic insomnia. Psychological therapy options include CBT-I and other interventions, such as stimulus control, relaxation strategies, and sleep restriction. ACP recommends that all adults receive CBT-I as the initial treatment for chronic insomnia disorder (strong recommendation, moderate-quality evidence). ACP recommends that clinicians use a shared decision-making approach, including a discussion of the benefits, harms, and costs of short-term use of medications, to decide whether to prescribe a medication in adults with chronic insomnia disorder in whom CBT-I alone was unsuccessful (weak recommendation, low-quality evidence). A review of the evidence found that eszopiclone, zolpidem, Belsomra, and Silenor may improve short-term global and sleep outcomes for adults with insomnia disorder (low- to moderate-quality evidence), but the comparative effectiveness and long-term efficacy of pharmacotherapies for insomnia are unknown.

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	12/15/2024

The policy effective date is in force until updated or retired.