# Drug Quantity Management Policy – Per Rx

**Policy:** Sedative Hypnotics Drug Quantity Management Policy – Per Rx

- Ambien® (zolpidem tablets – Sanofi-Aventis, generic)
- Ambien CR® (zolpidem extended-release tablets – Sanofi-Aventis, generic)
- Belsomra® (suvorexant tablets – Merck)
- Dayvigo® (lemborexant tablets – Eisai)
- Doral® (quazepam tablets – Galt, generic)
- Edluar® (zolpidem sublingual tablets – Meda)
- Estazolam tablets (generic only)
- Flurazepam capsules (generic only)
- Halcion® (triazolam tablets – Pfizer, generic)
- Lunesta® (eszopiclone tablets – Sunovion, generic)
- Quviviq™ (daridorexant tablets – Idorsia)
- Restoril® (temazepam capsules – Mallinckrodt, generic)
- Rozerem® (ramelteon tablets – Takeda, generic)
- Silenor® (doxepin tablets – Currax, generic)
- Zaleplon capsules (generic only)
- Zolpidem capsules (Almatica)
- Zolpidem sublingual tablets (generic only)
- Zolpimist® (zolpidem oral spray – Aytu) [discontinued]

**Review Date:** 09/18/2024

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***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.*

## Cigna National Formulary Coverage:

### Overview

All of the sedative hypnotics are indicated for the **treatment of insomnia**.[1-17,24] Refer to Table 1 for the specific indications of each of the sedative hypnotics.

**Table 1. Sedative Hypnotic Indications.[1-17,24]**

| Product | Indication |
|---|---|
| Ambien® (zolpidem tablets, generic) | Short-term treatment of insomnia characterized by difficulties with sleep initiation. It has been shown to decrease sleep latency for up to 35 days in controlled clinical trials. |
| Ambien CR® (zolpidem ER tablets, generic) | Treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Clinical trials support the duration of effect for up to 3 weeks and 24 weeks. |
| Belsomra® (suvorexant tablets) | Treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Patients should only take Belsomra if they have at least 7 hours remaining before their planned time of awakening. |
| Dayvigo® (lemborexant tablets) | Treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Patients should only take Dayvigo if they have at least 7 hours remaining before their planned time of awakening. |
| Doral® (quazepam tablets, generic) | Treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. The effectiveness of quazepam has been established in placebo-controlled clinical studies of 5 nights duration in acute and chronic insomnia. The sustained effectiveness of quazepam has been established in chronic insomnia in a sleep lab (polysomnographic) study of 28 nights duration. |
| Edluar® (zolpidem sublingual tablets) | Short-term treatment of insomnia characterized by difficulties with sleep initiation. Clinical trials were 4 to 5 weeks in duration. |

**Table 1 (continued). Sedative Hypnotic Indications.[1-17,24]**

| Product | Indication |
|---|---|
| Estazolam tablets (generic only) | Short-term management of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. There is evidence to support the ability of estazolam to enhance the duration and quality of sleep for intervals up to 12 weeks. |
| Flurazepam capsules (generic only) | Treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. |
| Halcion® (triazolam tablets, generic) | Short-term treatment of insomnia (generally 7 to 10 days) in adults. |
| Lunesta® (eszopiclone tablets, generic) | Treatment of insomnia. In controlled outpatient and sleep laboratory studies, eszopiclone administered at bedtime decreased sleep latency and improved sleep maintenance. Clinical trials support the duration of effect for up to 6 months. |
| Quviviq® (daridorexant tablets) | Treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Patients should only take Quviviq if they have at least 7 hours remaining before their planned time of awakening. |
| Restoril® (temazepam capsules, generic) | Short-term treatment of insomnia (generally 7 to 10 days). For patients with short-term insomnia, instructions in the prescription should indicate that temazepam be used for short periods of time (7 to 10 days). The clinical trials performed in support of efficacy were 2 weeks in duration with the final formal assessment of sleep latency performed at the end of treatment. |

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|---|---|
| Rozerem® (ramelteon tablets, generic) | Treatment of insomnia characterized by difficulty with sleep onset. Clinical trials support the duration of effect for up to 6 months. |
| Silenor® (doxepin tablets, generic) | Treatment of insomnia characterized by difficulty with sleep maintenance. Clinical trials support the duration of effect for up to 12 weeks. |
| Zaleplon capsules (generic only) | Short-term treatment of insomnia. Zaleplon has been shown to decrease the time to sleep onset for up to 30 days in controlled clinical studies. It has not been shown to increase total sleep time or decrease the number of awakenings. |
| Zolpidem capsules | Short-term treatment of transient insomnia characterized by difficulties with sleep initiation in adults younger than 65 years of age. |
| Zolpidem sublingual tablets (generic only) | For use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Patients should only take zolpidem sublingual tablets if they have ≥ 4 hours of bedtime remaining before the planned time of waking. |
| Zolpimist® (zolpidem oral spray) | Short-term treatment of insomnia characterized by difficulties with sleep initiation. Zolpidem has been shown to decrease sleep latency for up to 35 days in controlled clinical trials. |

ER – Extended-release.

Of note, doxepin is also available as generic oral capsules (10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg) and oral solution (10 mg/mL).[18] These higher dose formulations are recommended for use in patients with depression and/or anxiety of varying etiologies.

## Guidelines

The American Academy of Sleep Medicine (AASM) published a clinical guideline for the evaluation and management of chronic insomnia in adults (2008).[19] Insomnia is primarily diagnosed by clinical evaluation through a thorough sleep history and detailed medical, substance, and psychiatric history. The evaluation and differential diagnosis of insomnia can be aided by self-administered questionnaires, at-home sleep logs, symptom checklists, psychological screening tests, and bed partner interviews. At a minimum, patients should complete a general medical/psychiatric questionnaire to identify comorbid disorders; a sleepiness assessment (e.g., Epworth Sleepiness Scale) to identify sleepy patients and comorbid disorders of sleepiness; and a 2-week sleep log to identify general patterns of sleep-wake times and day-to-day variability. A sleep diary should be maintained prior to and during the course of active treatment and in the case of relapse or reevaluation in the long-term. 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 (e.g., stimulus control therapy or relaxation therapy) or the combination of cognitive therapy, stimulus control therapy, or 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).[20] 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. 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. An AASM practice guideline regarding behavioral and psychological treatments for insomnia was also published in 2021.[23] This highlights the importance of these treatments in the management of insomnia.

The American College of Physicians (ACP) developed a guideline on the management of chronic insomnia disorder in adults (2016).[21,22] Chronic insomnia can be managed with psychological therapy, pharmacologic therapy, or a combination of both. 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). ACP also notes that pharmacotherapies for insomnia may cause cognitive and behavioral changes and may be associated with infrequent but serious harms.

## POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of the sedative hypnotics. Quantity limits for each drug are provided below. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

## Drug Quantity Limits

| Product | Dosage Forms and Strengths | Retail Maximum Quantity per Rx | Home Delivery Maximum Quantity per Rx |
|---|---|---|---|
| Ambien®<br>(zolpidem tablets, generic) | 5 mg tablets<br>10 mg tablets | 30 tablets | 90 tablets |
| Ambien CR®<br>(zolpidem extended-release tablets, generic) | 6.25 mg extended-release tablets<br>12.5 mg extended-release tablets | 30 extended-release tablets | 90 extended-release tablets |

## Drug Quantity Limits (continued)

| Product | Dosage Forms and Strengths | Retail Maximum Quantity per Rx | Home Delivery Maximum Quantity per Rx |
|---|---|---|---|
| Belsomra®<br>(suvorexant tablets) | 5 mg tablets<br>10 mg tablets<br>15 mg tablets<br>20 mg tablets | 30 tablets | 90 tablets |
| Dayvigo®<br>(lemborexant tablets) | 5 mg tablets<br>10 mg tablets | 30 tablets | 90 tablets |
| Doral®<br>(quazepam tablets, authorized generic) | 15 mg tablets | 15 tablets | 15 tablets |
| Edluar®<br>(zolpidem SL tablets) | 5 mg SL tablets<br>10 mg SL tablets | 30 SL tablets | 90 SL tablets |
| Estazolam tablets<br>(generic only) | 1 mg tablets<br>2 mg tablets | 15 tablets | 15 tablets |
| Flurazepam capsules<br>(generic only) | 15 mg capsules<br>30 mg capsules | 15 capsules | 15 capsules |
| Halcion®<br>(triazolam tablets, generic) | 0.125 mg tablets<br>(generic only)<br>0.25 mg tablets | 15 tablets | 15 tablets |
| Lunesta®<br>(eszopiclone tablets, generic) | 1 mg tablets<br>2 mg tablets<br>3 mg tablets | 30 tablets | 90 tablets |
| Quviviq®<br>(daridorexant tablets) | 25 mg tablets<br>50 mg tablets | 30 tablets | 90 tablets |
| Restoril®<br>(temazepam capsules, generic) | 7.5 mg capsules<br>15 mg capsules<br>22.5 mg capsules<br>30 mg capsules | 15 capsules | 15 capsules |
| Rozerem®<br>(ramelteon tablets, generic) | 8 mg tablets | 30 tablets | 90 tablets |
| Silenor®<br>(doxepin tablets, generic) | 3 mg tablets<br>6 mg tablets | 30 tablets | 90 tablets |
| Zaleplon capsules<br>(generic only) | 5 mg capsules | 30 capsules | 90 capsules |
| | 10 mg capsules | 30 capsules | 90 capsules |
| Zolpidem capsules<br>(branded product) | 7.5 mg capsules | 30 capsules | 90 capsules |
| Zolpimist®<br>(zolpidem oral spray)<br>[discontinued] | 5 mg per spray<br>Supplied as a 4.5 mL bottle (30 sprays) and a 7.7 mL bottle (60 sprays) | 1 bottle | 3 bottles |
| Zolpidem SL tablets<br>(generic only) | 1.75 mg SL tablets<br>3.5 mg SL tablets | 30 SL tablets | 90 SL tablets |

SL – Sublingual.

**Sedative Hypnotics Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

**CRITERIA**

Zolpidem tablets (Ambien, generic), zolpidem extended-release tablets (Ambien CR, generic), zolpidem 7.5 mg capsules (branded product), Belsomra tablets, Dayvigo tablets, Edluar sublingual tablets, eszopiclone tablets (Lunesta, generic), Quviviq tablets, ramelteon tablets (Rozerem, generic), zolpidem sublingual tablets (generic to formerly available Intermezzo), doxepin tablets (Silenor, generic), zaleplon capsules (generic only), Zolpimist oral spray (discontinued)
No overrides recommended.

Zaleplon 10 mg capsules

**1.** Approve the requested quantity, not to exceed 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery, if the patient meets ONE of the approval criteria below (A, B, or C) [below] AND did not respond adequately to zaleplon 10 mg once daily.

Quazepam tablets (Doral, authorized generic),estazolam tablets (generic only), flurazepam capsules (generic only), triazolam tablets (Halcion, generic), temazepam capsules (Restoril, generic),

**1.** Approve if the patient meets ONE of the approval criteria below (A, B, or C):

**A) Acute Insomnia.** Approve a one-time override for 30 capsules or tablets at retail or home delivery if the patient meets ALL of the following criteria (i, ii, iii, iv, and v):
Note: Acute insomnia may be due to conditions such as stress resulting from bereavement or a traumatic event; an incurable progressive medical condition such as cancer; or chronic pain.

- **i.** Patient has received nightly therapy with the requested drug for < 60 days; AND
  Note: Authorization beyond 60 days for acute insomnia is NOT recommended.
- **ii.** Patient's insomnia is expected to persist for greater than 15 of the next 30 days, according to the prescriber; AND
- **iii.** Patient's insomnia will not be amenable to intermittent therapy with a sedative hypnotic (e.g., every other day or 3 or 4 nights per week treatment), according to the prescriber; AND
- **iv.** Patient has tried at least one form of behavioral therapy for insomnia; AND
  Note: Examples of behavioral therapy for insomnia include relaxation training, stimulus control therapy, or sleep restriction therapy.
- **v.** Patient has been evaluated for underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia and if necessary, the conditions are currently being addressed, according to the prescriber.

**B) Chronic Insomnia**. Approve the requested medication for the duration noted if the patient meets ONE of the following conditions (i or ii):

Note: Chronic insomnia is defined as insomnia that occurs greater than 4 nights weekly for greater than 3 months in duration.

**i.** Initial Therapy. Approve 30 capsules or tablets per dispensing at retail or 90 capsules or tablets per dispensing at home delivery for 6 months if the patient requires nightly (daily) therapy and meets ONE of the following criteria (a or b):

**a)** Patient is being followed by, or has consulted with, a sleep specialist or a sleep center regarding the management of insomnia; OR

**b)** Patient meets ALL of the following criteria (1, 2 and 3):

**(1)** Patient has tried at least one form of behavioral therapy for insomnia; AND

Note: Examples of behavioral therapy for insomnia include relaxation training, stimulus control therapy, or sleep restriction therapy.

**(2)** Patient is not currently taking non-prescription stimulants (e.g., caffeine) and/or prescription stimulants, if medically appropriate (e.g., methylphenidate, amphetamine products); AND

**(3)** Patient has been evaluated for underlying psychiatric and/or medical conditions that may cause or exacerbate insomnia and if necessary, the conditions are currently being addressed, according to the prescriber.

**ii.** Patient is Currently Receiving the Requested Drug. Approve 30 capsules or tablets per dispensing or 90 capsules or tablets per dispensing at home delivery for 1 year if the patient requires nightly (daily) therapy AND meets BOTH of the following (a and b):

**a)** Patient has already received nightly therapy with the requested drug for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy should be considered under criterion B.i. (Chronic Insomnia, Initial Therapy).

**b)** The requested drug is still effective, as determined by the prescriber.

**C) Major Depressive Disorder, Bipolar Disorder, or Generalized Anxiety Disorder**. Approve the requested medication for the duration noted if the patient meets ONE of the following conditions (i or ii):

**i.** Initial Therapy. Approve 30 capsules or tablets per dispensing at retail or 90 capsules or tablets per dispensing at home delivery for 3 months, if the patient is receiving drug therapy to treat either major depressive disorder, bipolar disorder, or generalized anxiety disorder.

**ii.** Patient is Currently Receiving the Requested Drug. Approve 30 capsules or tablets per dispensing at retail or 90 capsules or tablets per dispensing at home delivery for 1 year if the patient meets ALL the criteria below (a, b, c, d, and e):

**a)** Patient is receiving drug therapy to treat either major depressive disorder, bipolar disorder, or generalized anxiety disorder; AND

**b)** Patient has already received nightly (daily) therapy with the requested drug for at least 3 months; AND

Note: A patient who has received < 3 months of therapy or who is restarting therapy should be considered under criterion C.i. (Major Depressive Disorder, Bipolar Disorder, or Generalized Anxiety Disorder, Initial Therapy).

**c)** Patient has a diagnosis of chronic insomnia and requires nightly (daily) therapy for treatment; AND
Note: Chronic insomnia is defined as insomnia that occurs greater than 4 nights weekly for greater than 3 months in duration.

**d)** Patient has tried at least one form of behavioral therapy for insomnia; AND
Note: Examples of behavioral therapy for insomnia include relaxation training, stimulus control therapy, or sleep restriction therapy.

**e)** Patient is not currently taking non-prescription stimulants (e.g., caffeine) and/or prescription stimulants, if medically appropriate (e.g., methylphenidate, amphetamine products).

## REFERENCES


1. Ambien® tablets [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; February 2022.
2. Sonata® capsules [prescribing information]. New York, NY: Pfizer; August 2019.
3. Restoril® capsules [prescribing information]. Hazelwood, MO: Mallinckrodt; January 2023.
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5. Edluar® sublingual tablets [prescribing information]. Somerset, NJ: Meda; August 2019.
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11. Silenor® tablets [prescribing information]. Morristown, NJ: Currax; October 2020.
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24. Zolpidem 7.5 mg capsules [prescribing information]. Morristown, NJ: Almatica; May 2023.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| New Policy | **Doral (quazepam 15 mg tablets, authorized generic)**: New quantity limits of 15 tablets per dispensing at retail and home delivery. Clinical override criteria apply.<br><br>**Estazolam 1 mg and 2 mg tablets**: New quantity limits of 15 tablets per dispensing at retail and home delivery. Clinical override criteria apply.<br><br>**Flurazepam 15 mg and 30 mg capsules**: New quantity limits of 15 capsules per dispensing at retail and home delivery. Clinical override criteria apply.<br><br>**Halcion (triazolam 0.125 mg [generic only] and 0.25 mg tablets, generic)**: New quantity limits of 15 tablets per dispensing at retail and home delivery. Clinical override criteria apply.<br><br>**Restoril (temazepam 7.5 mg, 15 mg, 22.5 mg, 30 mg capsules, generic)**: New quantity limits of 15 capsules per dispensing at retail and home delivery. Clinical override criteria apply.<br><br>**Zaleplon 10 mg capsules:** Quantity limits were changed to 30 capsules per dispensing at retail and 90 capsules per dispensing at home delivery (previous limits were 60 capsules per dispensing at retail and 180 capsules per dispensing at home delivery). Clinical override criteria apply. | 09/18/2024 |