

Clinical Policy: Agents for Insomnia

Reference Number: AZ.CP.PMN.1016

Effective Date: 07.16

Last Review Date: 04.20

Line of Business: Arizona Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The following are sleep medications indicated for insomnia that require prior authorization: suvorexant (Belsomra®), zolpidem CR (Ambien CR®), zolpidem sublingual tablets (Edluar®, Intermezzo®), zolpidem spray (Zolpimist®), estazolam (Prosom), Eszopiclone (Lunesta), Flurazepam (Dalmane), lemborexant (Dayvigo), ramelteon (Rozerem®), doxepin (Silenor®), temazepam (restoril) 7.5mg & 22.5mg, triazolam (Halcion), and zaleplon (Sonata)

AHCCCS preferred drugs in this class include: Eszopiclone, Rozerem (brand only), Temazepam 15mg & 30mg, Zolpidem 5mg & 10mg.

AHCCCS non-preferred drugs in this class include: Ambien, Belsomra, Dayvigo, Edluar, estazolam, flurazepam, Halcion, Intermezzo, Lunesta, Prosom, ramelteon, Silenor, Sonata, triazolam, zaleplon, Zolpidem CR, Zolpimist.

FDA approved indications

Lemborexant (Dayvigo) is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Edluar and Zolpimist are indicated for short-term treatment of insomnia characterized by difficulties with sleep initiation.

Eszopiclone (Lunesta) is indicated for the treatment of insomnia.

Estazolam (Prosom) and flurazepam are indicated for short term treatment of insomnia characterized by difficulty falling asleep, frequent nocturnal awakenings, and/or early morning awakenings.

Zolpidem CR is indicated for the short-term treatment of insomnia characterized by difficulty with sleep onset and/or sleep maintenance.

Intermezzo is indicated for treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep.

Rozerem is indicated for treatment of insomnia characterized by difficulty with sleep onset.

Silenor is indicated for treatment of insomnia characterized by difficulties with sleep maintenance.

Triazolam (Halcion) and zaleplon (Sonata) are indicated for the short-term treatment of insomnia. Belsonra is indicated for treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Arizona Complete Health that the above listed medications are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Insomnia (must meet all):

1. Diagnosis of insomnia;
2. For Rozerem (BRAND) only: one of the following (a **OR** b):
 - a. Failure of temazepam and zolpidem, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Previous history of substance abuse;
3. For Silenor only: both of the following (a **AND** b):
 - a. Failure of trials of 2 preferred sedative, hypnotic agents (eszopiclone, temazepam 15 mg & 30 mg, and zolpidem) unless contraindicated or clinically significant adverse effects are experienced;
 - b. Failure of low dose doxepin unless contraindicated or clinically significant adverse effects are experienced;
4. For zolpidem sublingual tablets (Intermezzo) only (must meet all):
 - a. Failure of trials of 2 preferred sedative, hypnotic agents (eszopiclone, temazepam 15 mg & 30 mg, and zolpidem) unless contraindicated or clinically significant adverse effects are experienced;
 - b. Documentation of middle of the night awakenings;
 - c. Dose does not exceed 1.75mg/day for women, and 3.5mg/day for men;
5. For Edluar only: Documentation of inability to swallow pills;
6. For all other Non-Preferred sedative, hypnotic agents: failure of trials of 2 preferred sedative, hypnotic agents (eszopiclone, temazepam 15 mg & 30 mg, and zolpidem) unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed FDA max daily dosing. Refer to *Section V. Dosage and Administration*.

Approval duration: 6 months

II. Continued Therapy

A. Insomnia (must meet all):

1. Currently receiving medication via a health plan affiliated with Centene

- Corporation or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., no significant toxicity);
 3. If request is for a dose increase, new dose does not exceed FDA max approved daily dose. Refer to *Section V. Dosage and Administration*
- Approval duration: 12 months**

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – AZ.CP.PMN.53 for Arizona Medicaid.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
eszopiclone (Lunesta)	1 mg PO	3 mg/day
temazepam (Restoril)	Adults: 15 - 30 mg PO Elderly: 7.5 - 15 mg PO	30 mg/day
zolpidem (Ambien)	Adults: 5-10 mg PO Elderly: 5 mg PO	10 mg/day
doxepin Solution doxepin Capsules	Adults: 3-6 mg Elderly: 3 mg Adults: 10-50mg	6mg/day
Rozerem (ramelteon) – BRAND only	8 mg PO HS	8 mg/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

See Individual Package Inserts

Appendix D: General Information

- Because sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient.

- Rozerem is a melatonin receptor agonist, Silenor is a histamine H1 receptor antagonist, and Belsomra and Dayvigo are orexin receptor antagonists. These agents do not work through the GABA-A receptors, as do the other available agents in this class.
- Silenor is not a scheduled controlled substance.
- Zolpidem has a Micromedex Class IIa indication for improving sleep in patients with SSRI induced insomnia. The insomnia had been ongoing for two weeks while on the SSRI.
- The recommended initial doses for women and men are different because zolpidem clearance is lower in women
- Intermezzo is not indicated when patient has fewer than 4 hours of bedtime before planned time of waking.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Belsomra (suvorexant)	10 mg – 20 mg PO QHS	20 mg/day
Dayvigo (lemborexant)	5 mg PO taken QHS	10 mg/day
estazolam (Prosom)	1-2 mg QHS	2 mg/day
eszopiclone (Lunesta)	Adults: 1-3 mg PO Q HS Elderly: 1-2 mg PO Q HS	Adults: 3mg/day Elderly: 2mg/day
flurazepam (Dalmane)	Adults: 15 - 30 mg PO QHS Elderly: 15 mg PO QHS Generally not recommended in the elderly due to long half-life of active metabolite	30 mg/day
Rozerem (ramelteon)	Adults: 8 mg PO QHS	8 mg/day
temazepam (Restoril)	7.5 to 30 mg PO QHS	30 mg/day
triazolam (Halcion)	Adults: 0.125 - 0.5 mg PO QHS	Adults: 0.5 mg/day Elderly: 0.25 mg/day
Zolpimist (zolpidem oral spray)	Women & Elderly: 5 mg PO QHS immediately before bedtime Men: 5-10 mg PO QHS immediately before bedtime	10 mg/day
zaleplon (Sonata)	Adults: 10 mg PO QHS Elderly: 5 mg PO QHS	Adults: 20 mg/day Elderly: 10 mg/day
Silenor (doxepin)	Adults: 3-6 mg PO QHS	6 mg/day
zolpidem (Ambien)	Adults: 5-10 mg PO	10 mg/day

Indication	Dosing Regimen	Maximum Dose
	Elderly: 5 mg PO	
zolpidem extended release (Ambien CR)	Adults: 6.25-12.5 mg PO QHS	Elderly: 6.25 mg PO QHS
zolpidem SL tabs (Edluar, Intermezzo)	Edluar: Women – 5 mg SL Men – 5 to 10 mg SL Intermezzo: Women & Elderly - 1.75 mg SL Men - 3.5 mg SL QD PRN	Edluar: 10 mg/day Intermezzo: 3.5 mg/day

VI. Product Availability

Drug Name	Availability
Edluar (zolpidem SL tablets)	Sublingual tablets: 5 mg, 10 mg
Estazolam (Prosom)	Tablets: 1 mg, 2 mg
Eszopiclone (Lunesta)	Tablets: 1 mg, 2 mg, 3 mg
Flurazepam (Dalmane)	Capsules: 15 mg, 30 mg
zolpidem SL tablets (Intermezzo)	Sublingual tablets: 1.75 mg, 3.5 mg
Zolpimist (zolpidem oral spray)	Oral spray: 5 mg per actuation
Rozerem (ramelteon)	Tablets: 8 mg
Silenor (doxepin)	Tablets: 3 mg, 6 mg
Triazolam (Halcion)	Tablets: 0.125 mg, 0.25 mg
Belsomra (suvorexant)	Tablets: 5 mg, 10 mg, 15 mg, 20 mg
Dayvigo (lemborexant)	Tablets: 5 mg, 10 mg
Zolpidem CR	Tablets: 6.25 mg, 12.5 mg
Zaleplon (Sonata)	Capsules: 5 mg, 10mg

VII. References

1. Edluar [Prescribing Information] Somerset, NJ: Meda Pharmaceuticals, Inc.; October 2014.
2. Zolpimist [Prescribing Information] Louisville, KY: MAGNA Pharmaceuticals. December 2008.
3. Rozerem [Prescribing Information] Deerfield, IL: Takeda Pharmaceuticals America Inc. November 2010.
4. Intermezzo [Prescribing Information] Stamford, CT: Purdue Pharma L.P. September 2015.
5. Silenor [Prescribing Information] Morristown, NJ: Pernix Therapeutics, LLC, Inc. March 2010.

6. Belsomra [Prescribing Information] Whitehouse Station, NJ: Merck & Co, Inc.; May 2016.
7. Ambien CR [Prescribing Information] Bridgewater, NJ: Sanofi-Aventis U.S. LLC. March 2017.
8. Dayvigo Prescribing Information. Woodcliff Lake, NJ: Eisai Inc.; December 2019.
9. Micromedex® Healthcare Series (Internet Database). Greenwood Village, CO:
10. Thompson Healthcare. Updated periodically. Accessed March 2018
11. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed May 2018

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; annual review, no significant changes; Addition of other non-benzodiazepine insomnia agents (Edular, Intermezzo, Rozerem, Silenor, Zolpidem CR, Zolpimist) to criteria.	03.18	04.18
Added estazolam, flurazepam, triazolam, Silenor, eszopiclone, zaleplon to the PA required list under “Description” and updated medications in “Therapeutic Alternatives” based on AHCCCS drug list. Changed name from “Non-benzodiazepine” to “Non-preferred”	05.18	07.18
Changed name from “Non-preferred Agents for Insomnia” to “Agents for Insomnia”, since Rozerem is preferred but require prior authorization; Added max dose for Intermezzo	04.19	07.19
Added criteria for eszopiclone and Edluar; Updated criteria for all other Non-Preferred sedative, hypnotic agents: failure of a trial of 2 preferred sedative, hypnotic agents (eszopiclone, Rozerem, temazepam, and zolpidem); Updated Appendix C, Section V, and Section VI; Renumber to AZ.CP.PMN.1016; Added section for AHCCCS preferred products.	12.19	01.20
Added Dayvigo to the AHCCCS non-preferred drugs and detailed dosing.	04.20	04.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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Agents for Insomnia



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