Clinical Policy: Non-Preferred Agents for Insomnia
Reference Number: AZ.CP.PHAR.10.11.23
Effective Date: 07.16
Last Review Date: 07.18
Line of Business: Medicaid- Arizona

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®), estazolam (Prosom), Eszopiclone (Lunesta),Flurazepam(Dalmane), (ramelteon (Rozerem®), doxepin (Silenor®), triazolam (Halcion), zaleplon (Sonata) and zolpidem spray (Zolpimist®).

FDA approved indications

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.

Belsomra is indicated for treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Policy/Criteria

Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

Policy/Criteria

CLINICAL POLICY

Non-Preferred Insomnia Medications

Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® 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. Failure of a trial of 2 formulary sedative, hypnotic agents (temazepam and zolpidem) unless contraindicated or clinically significant adverse effects are experienced.
3. For Silenor only: Failure of low dose doxepin unless contraindicated or clinically significant adverse effects are experienced
4. For Rozerem only: one of the following (a or b):
   a. Failure of a trial of 2 preferred agents unless contraindicated or clinically significant adverse effects are experienced.
   b. Patient has a previous history of substance abuse.
5. For Intermezzo only: documentation of middle of the night awakenings and only needs Short acting dose
6. Dose does not exceed FDA max daily dosing. Refer to Section V. Dosage and Administration

Approval duration: 6 months

B. Other diagnoses/indications

Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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 policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key-N/A

Appendix B: 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 is an orexin receptor antagonist. These three 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.

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/Maximum Dose
temazepam (Restoril)	Adults: 15 - 30 mg PO QHS Elderly: 7.5 - 15 mg PO QHS	30 mg/day
zolpidem (Ambien)	Adults: 5-10 mg PO QHS Elderly: 5 mg PO QHS	10 mg/day
Doxepin Sol Doxepin Capsules	Adults: 3-6 mg Elderly: 3 mg Adults:10-50mg	6mg/day

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Belsomra (suvorexant)	10 mg – 20 mg PO QHS	20 mg PO QD
Edluar (zolpidem SL)	Women & Elderly: 5 mg SL QHS Men: 5 or 10 mg SL QHS	10 mg/day
Flurazepam(Dalmane)	15- 30mg Q HS	Elderly: 15 mg/day Adults: 30 mg/day Adolescents ≥ 15 years: 30 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	30 mg/day
Intermezzo (zolpidem SL tabs)	Women & Elderly: 1.75 mg SL QD PRN Men: 3.5 mg SL QD PRN	3.5 mg/day
Rozerem (ramelteon)	Adults: 8 mg PO QHS	8 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	Adults: 6 mg PO QHS	6 mg/day
zolpidem extended release (Ambien CR)	Adults: 6.25-12.5 mg PO QHS	Elderly: 6.25 mg PO QHS

VI. Product Availability

Drug	Availability
Edluar	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
Intermezzo	Sublingual tablets: 1.75 mg, 3.5 mg
Zolpimist	Oral spray: 5 mg per actuation
Rozerem	Tablets: 8 mg
Silenor	Tablets: 3 mg, 6 mg
Triazolam (Halcion)	Tablets: 0.125 mg, 0.25 mg
Belsomra	Tablets : 5 mg, 10 mg, 15 mg, 20 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. Micromedex® Healthcare Series (Internet Database). Greenwood Village, CO:
9. Thompson Healthcare. Updated periodically. Accessed March 2018
10. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed May 2018

CLINICAL POLICY

Non-Preferred Insomnia Medications

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

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 plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.
The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

CLINICAL POLICY

Non-Preferred Insomnia Medications

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.