Pharmacy Medical Necessity Guidelines: Hypnotic Agents

Effective: September 15, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Zolpidem tartrate tablet (Ambien) is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

Zolpidem tartrate 1.75 mg and 3.5 mg sublingual tablet 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.

Edluar® (zolpidem tartrate) sublingual tablet is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

Zolpidem extended-release (Ambien CR) is indicated for the short-term treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance (as measured by wake time after sleep onset).

Belsomra® (suvorexant) and DayVigo (lemborexant) are orexin receptor antagonists indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Eszopiclone is indicated for the treatment of insomnia. In controlled outpatient and sleep laboratory studies, Lunesta administered at bedtime decreased sleep latency and improved sleep maintenance.

Ramelteon (Rozerem) is indicated for the treatment of insomnia characterized by difficulty with sleep onset.

Zaleplon (Sonata) is indicated for the short-term treatment of insomnia. Sonata has been shown to decrease the time to sleep onset for up to 30 days in controlled clinical studies.

Generic name (Brand name)	Strengths	Maximum recommended daily dose*
Eszopiclone (Lunesta)	1mg, 2mg, 3mg	3 mg/day
Ramelteon (Rozerem)	8mg	8 mg/day
Suvorexant (Belsomra)	5 mg, 10 mg, 15 mg, 20 mg	20 mg/day
Lemborexant (DayVigo)	5 mg, 10 mg	10 mg/day
Zaleplon (Sonata)	5mg, 10mg	20 mg/day
Zolpidem, IR (Ambien)	5mg, 10mg	10 mg/day
Zolpidem, ER (Ambien CR)	6.25mg, 12.5mg	12.5 mg/day
Zolpidem, SL tablets (Edluar)	5mg, 10mg	10 mg/day
Zolpidem, SL tablets (Intermezzo)	1.75 mg, 3.5 mg	1.75 mg/day for women, 3.5 mg/day for men

***The recommended initial dosage of zolpidem immediate-release tablets for sleep onset is 5 mg for women and 5 mg or 10 mg for men. The recommended initial dosage of zolpidem controlled-release tablets for sleep onset is 6.25 mg for women and 6.25 mg or 12.5 mg for men.

Since 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. The failure of insomnia to remit following a reasonable period of treatment may indicate the presence of a primary psychiatric and/or medical illness that requires evaluation. Worsening of insomnia, or the emergence of new cognitive or behavioral abnormalities, may be the result of an unrecognized underlying psychiatric or physical disorder requiring further evaluation.

COVERAGE GUIDELINES

The plan may authorize coverage of a nonpreferred hypnotic agent for Members when **ALL** of the following criteria for a particular regimen are met:

Initial

1. Member had an inadequate response (defined as at least 30 days' duration), intolerance, or contraindication to **ALL** of the following:
   a) zaleplon
   b) zolpidem immediate-release

AND

2. **Belsomra (suvorexant) and DayVigo (lemborexant) only:** Member had an inadequate response (defined as at least 30 days' duration, intolerance, or contraindication to both of the following: zolpidem controlled-release and eszopiclone.

Reauthorization

1. Documentation that the Member has been re-evaluated in the previous year and continued management of insomnia with medication is medically necessary

LIMITATIONS

1. The coverage of Belsomra (suvorexant), DayVigo (Lemborexant), eszopiclone, ramelteon, zaleplon, and zolpidem is limited to one unit per day.
2. The length of approval will be for one year.
3. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.
4. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception, but will be considered on an individual basis for prior authorization.

CODES

None

REFERENCES

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17. Walsh JK, Fry J, Erwin CW et al. Efficacy and tolerability of 14-day administration of zaleplon 5mg and 10mg for the treatment of primary insomnia. *Clin Drug Invest*. 1998; 16:347-54.
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19. Zolpidem tartrate sublingual [package insert]. Chestnut Ridge, NY: Par Pharmaceutical; October 2019.
20. Zolpimist (zolpidem) [package insert]. Flemington, NJ: NovaDel Pharma Inc.; August 2019.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: Effective December 1, 2023, updated reauthorization criteria to require documentation that Member has been re-evaluated in the previous year and continued management of insomnia with medication is medically necessary.
2. September 10, 2024: Administrative change to fax number.
3. September 9, 2025: No changes
4. September 15, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.