Pharmacy Medical Necessity Guidelines: Hypnotic Agents

Effective: July 20, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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

OVERVIEW

FDA-APPROVED INDICATIONS

Ambien® (zolpidem tartrate conventional tablets) is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Ambien has been shown to decrease sleep latency and increase the duration of sleep for up to 35 days in controlled clinical studies. The clinical trials performed in support of efficacy were four to five weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.

Ambien CR® (zolpidem extended-release) is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance (as measured by wake time after sleep onset). The clinical trials performed in support of efficacy were up to 3 weeks (using polysomnography measurement up to 2 weeks in both adult and elderly patients) and 24 weeks (using patient-reported assessment in adult patients only) in duration.

DayVigo™ (lemborexant) is an orexin receptor antagonist indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or maintenance.

Edluar® (zolpidem tartrate) sublingual tablet is indicated for the 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.

Lunesta® (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. The clinical trials performed in support of efficacy were up to six months in duration. The final formal assessments of sleep latency and maintenance were performed at four weeks in the six-week study (adults only), at the end of both two-week studies (elderly only) and at the end of the six-month study (adults only).

Rozerem™ (ramelteon) is indicated for the treatment of insomnia characterized by difficulty with sleep onset. The clinical trials performed in support of efficacy were up to 6 months in duration. The final formal assessments of sleep latency were performed after 2 days of treatment during the crossover study (elderly only), at 5 weeks in the 6-week studies (adults and elderly), and at the end of the 6-month stud (adults and elderly).

Sonata® (zaleplon) 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. It has not been shown to increase total sleep time or decrease the number of awakenings. The clinical trials performed in support of efficacy ranged from a single night to five weeks in duration. The final formal assessments of sleep latency were performed at the end of treatment.

Belsomra® (suvorexant) is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

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

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.

Upon renewal

1. The Member had an office visit within the past year, was reassessed for the condition, and continued therapy with the medication is considered medically necessary

LIMITATIONS

1. The coverage of 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

1. Ambien [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; August 2019.
2. Ambien CR [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; August 2019.
3. DayVigo [package insert]. Woodcliff, NJF: Eisai, Inc; December 2019.
4. Edluar [package insert]. Somerset, NJ: Meda Pharmaceuticals Inc; August 2019.
5. Elie R, Rüther E, Farr I et al for the Zaleplon Study Group. Sleep latency is shortened during 4 weeks of treatment with zaleplon, a novel nonbenzodiazepine hypnotic. *J Clin Psychiatry*. 1999; 60:536-44.

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19. Zolpimist [package insert]. Flemington, NJ: NovaDel Pharma Inc.; August 2019.
20. Belsomra [package insert]. Whitehouse Station, NJ: Merck; March 2020.

APPROVAL HISTORY

June 4, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. March 10, 2015: Approval duration modified to one year.
2. June 9, 2015: Added criteria for Belsomra; added criteria for children less than 6 years of age.
3. January 1, 2016: Administrative change to rebranded template.
4. August 9, 2016: Updated criteria for children less than 6 years of age.
5. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Removed Pediatric Behavioral Health Medication (PBHMI) criteria and language.
6. August 8, 2017: No changes.
7. November 13, 2018: Administrative changes made to template.
8. October 15, 2019: No changes.
9. April 14, 2020: Effective July 1, 2020, updated the criteria for Belsomra to require trial and failure with eszopiclone, which is now covered without PA.
10. June 9, 2020: Added criteria for DayVigo to the MNG.
11. July 14, 2020: Administrative update, added language regarding samples to the limitations section of the MNG.

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.