Pharmacy Medical Necessity Guidelines: Insomnia Treatments

Effective: June 15, 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

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.

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 three weeks (using polysomnography measurement up to two weeks in both adult and elderly patients) and 24 weeks (using patient-reported assessment in adult patients only) in duration.

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

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

Intermezzo® (zolpidem) sublingual tablets are indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep.

Lunesta® (eszopiclone) is indicated for the treatment of insomnia. In controlled outpatient and sleep laboratory studies, Lunesta (eszopiclone) 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 preformed in support of efficacy were up to six months in duration. The final formal assessments of sleep latency were performed after two days of treatment during the crossover study (elderly only), at five weeks in the six 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 (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. 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.

Zolpimist™ (zolpidem) oral spray is indicated for short-term treatment of insomnia characterized by difficulties with sleep initiation. Zolpimist (zolpidem) has been shown to decrease sleep latency for up to 35 days in controlled trials.

COVERAGE GUIDELINES

Note: Prescriptions that meet the initial step therapy requirements, will adjudicate **automatically** at the point of service. If the Member does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan using the Universal Pharmacy Medical Review Request Form for Members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

Drug	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
Step-1		
zaleplon	Covered	Covered
zolpidem tartrate		
eszopiclone		
Step-2		
ramelteon	Requires prior use of a drug on Step-1 or Step-2	Requires prior use of a drug on Step-1 or Step-2
zolpidem tartrate CR		
Zolpidem tartrate sublingual		
Step-3		
Belsomra®	Requires prior use of a drug on Step-2 or Step-3	Requires prior use of a drug on Step-2 or Step-3
Dayvigo		
Zolpimist™		

Automated Step Therapy Coverage Criteria
The following stepped approach applies to coverage of the Step-2 and Step-3 medications by the plan:

Step 1: Medications on Step-1 are covered without prior authorization
Step 2: The plan may cover Step-2 medications if the following criteria are met:
1. The Member has had a trial of a Step-1 or Step-2 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan

Step 3: The plan may cover Step-3 medications if the following criteria are met:
2. The Member has had a trial of a Step-2 or Step-3 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan

Note: The plan may cover medications on Step-2 or Step-3 if a Member has received a **non-covered** medication within the previous 180 days listed below under the limitations section.

Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale
The following stepped approach applies to insomnia treatments covered by the plan:

Step 2: The plan may cover medications on Step-2 if the following criteria are met:
1. The Member has had previous trial of a Step-1 or Step-2 medication as evidenced by physician documented use

OR

2. The Member has a physician documented contraindication or intolerance to all Step-1 medication

Step 3: The plan may cover medications on Step-3 if the following criteria are met:

1. The Member has had a trial of a Step-2 or Step-3 medication as evidenced by physician's documented use

OR

2. The Member has a physician documented contraindication or intolerance to all Step-1 and Step-2 medications

Note: The plan may cover medications on Step-2 or Step-3 if a Member has received a **non-covered** medication, listed below under the limitations section, as evidenced by physician documented use.

LIMITATIONS

1. Medications on Step-2 and Step-3 are not covered unless the above step therapy criteria are met.
2. Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception, but will be considered on an individual basis for prior authorization.
3. The brand-name products Ambien, Ambien CR, Edluar, Intermezzo, Lunesta, Rozerem, and Sonata are not covered for all Tufts Health Plan MA/RI formularies. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives.
4. The following quantity limitations apply to any strength and combination of eszopiclone, zaleplon, zolpidem tartrate, zolpidem tartrate CR, Ambien, Ambien CR, Belsomra, Dayvigo, Edluar, Intermezzo, Lunesta, Rozerem and/or Sonata:
   - At retail pharmacy – 10 capsules/tablets per 30 days
   - At mail order pharmacy – 30 capsules/tablets per 90 days
5. The following quantity limitation applies to Zolpimist:
   - At retail pharmacy – 1 metered spray unit per 30 days
   - At mail order pharmacy – 3 metered spray units per 90 days
6. Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Quantity Limitations and submit a formulary exception request for those Members requiring higher quantities.
7. Exception requests for additional quantities of the drugs included in this program may be authorized in 12-month intervals.

CODES

None

REFERENCES

1. Ambien (zolpidem) [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; March 2017.
2. Ambien CR (zolpidem extended-release) [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; March 2017.
3. Belsomra (suvorexant)[package insert]. Whitehouse Station, NJ: Merck & Co.; March 2016.
4. Dayvigo (lemborexant)[package insert]. Woodcliff Lake, NJ: Eisai Inc.; April 2020.
5. Edluar (zolpidem) [package insert]. Somerset, NJ: Meda Pharmaceuticals Inc; October 2014.
6. 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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9. Hurst M, Noble S. Zaleplon. *CNS Drugs*. 1999;11:387-92.
10. Intermezzo [package insert]. Stamford, CT: Purdue Pharma L.P.; July 2015.
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16. Rozerem (ramelteon) [package insert]. Deerfield, IL: Takeda Pharmaceuticals American Inc.; December 2018.
17. Sonata (zaleplon) [package insert]. Bristol, TN: King Pharmaceuticals Inc.; November 2016.
18. Wagner J, Wagner ML, Hening WA. Beyond benzodiazepines: alternative pharmacologic agents for the treatment of insomnia. *Ann Pharmacotherapy*. 1998;32:680-91.
19. 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.
20. Zolpimist (zolpidem) [package insert]. Flemington, NJ: NovaDel Pharma Inc.; March 2016.

APPROVAL HISTORY

May 8, 2007: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- November 13, 2007: Added Tufts Health Plan Commercial Formulary to Step Therapy Program.
- May 13, 2008: Added zaleplon to Step-1 of step therapy program. Added dispensing limitation for zaleplon. Moved Sonata to Non-covered status for the Generic Focused Formulary
- July 8, 2008: Added limitation that exception requests for additional quantities of the drugs listed above may be authorized in 12-month intervals. Added dispensing limitations of 30 capsules/tablets per 90 days at mail to all drugs included in this step therapy program.
- March 10, 2009: Moved Sonata to Non-covered status for Tufts Health Plan Commercial and R.I. formularies.
- September 8, 2009: Added Edluar (zolpidem tartrate) to criteria on non-covered status. Added Insomnia Treatments step therapy program to Tufts Health Plan Medicare Preferred MA-PD and PDP formularies. Added note to limitations for Tufts Health Plan Medicare Preferred MA-PD and PDP Members to refer to the Comprehensive Formulary listing on the Web for individual quantity limitations.
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
- September 14, 2010: No changes.
- November 9, 2010: Added zolpidem tartrate CR to Step-2 of the Insomnia Treatment Medical Necessity Guidelines. Added zolpidem tartrate CR to the limitations with the QL of 10 tablets per 30 days. Removed the word "Dispensing" from the Pharmacy Medical Necessity Guidelines for Drugs with Dispensing Limitations, and replaced it with "Quantity."
- September 9, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
- November 15, 2011: Removed the Step-3 wording and replaced with coverage criteria for non-covered drugs.
- June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs. Clarified step criteria to reflect that Step-2 drugs are prerequisites for drugs on Step-2.
- August 14, 2012: Removed reference to Tufts Health Plan Medicare Preferred MA-PD and PDP from limitations section. Removed the non-covered drugs Ambien®, Ambien CR™, Eduard® and Sonata® from the step therapy grid and added them to the limitations section. Added the non-covered drugs Intermezzo and Zolpimist to the limitations section. Added note that non-covered products (Ambien, Ambien CR, Edluar, Intermezzo, Sonata and Zolpimist) may qualify as prerequisites for Step-2 medications. Added use of samples or vouchers/coupons for brand name medications limitation.
- February 12, 2013: Added Intermezzo and Zolpimist to Step-2 of the Medical Necessity Guidelines for Comm MA/RI, still not covered for GFF.
- October 8, 2013: Administrative update: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
- February 11, 2014: No changes
- April 1, 2014: Administrative update: removed language pertaining to the Generic Focused Formulary and added the EHB MA/RI Formulary.
- May 13, 2014: Added eszopiclone (generic Lunesta) to Step-2, moved Lunesta to Step-3, and added criteria for Step-3.
- May 12, 2015: Moved Lunesta to not covered for the MA/RI EHB formularies.
- June 9, 2015: Added Belsomra to Step-3 of the Medical Necessity Guidelines.
- August 11, 2015: Moved eszopiclone to Step-1 of the Medical Necessity Guidelines.
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- April 12, 2016: Added generic zolpidem tartrate sublingual to Step-2. Moved Intermezzo® to Step-3 for Large group formularies and to not covered for the MA/RI EHB formularies.

- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- April 10, 2018: No Changes
- September 18, 2018: Moved Zolpimist to Step 3. Administrative update to reflect that Lunesta and Intermezzo have moved to NC for Commercial Large groups.
- August 13, 2019: Effective January 1, 2020, moved Rozerem to non-covered status for all Commercial formularies, due to launch of the generic. Updated step therapy criteria to require trial and failure with one, or contraindication to all lower step medications.
- June 9, 2020: Added Dayvigo to Step-3 of the Medical Necessity Guidelines. Removed sample language exclusion from step therapy criteria and updated limitation section to include the following language: Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

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.