

Document ID#: 2111794
Subject: Insomnia Treatments
Effective Date: July 8, 2008

Clinical Documentation and Prior Authorization Required	√	Type of Review - Case Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Administrative Process (Internal Use Only)	LPN

Note: Background, applicable product and disclaimer information can be found on the last page.

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 used as a hypnotic agent for the short-term management of insomnia, generally for periods not exceeding 7-10 days in duration. Because of its short half-life, zolpidem tartrate may be of particular benefit for the initiation of sleep (e.g. decreasing sleep latency). In controlled clinical trials, zolpidem tartrate reportedly has been effective in decreasing sleep latency and prolonging total sleep time for periods up to 35 days in duration.

Lunesta® (eszopiclone) is approved as a hypnotic agent for the management of transient and chronic insomnia. In controlled clinical studies, eszopiclone reportedly has been shown to have continued efficacy in decreasing sleep latency and prolonging total sleep time when administered nightly for periods up to 6 months in duration.

Rozerem™ (ramelteon) is indicated for the management of insomnia characterized by difficulty with sleep onset. In one clinical trial, sleep latency was reduced by up to 39% with ramelteon vs. placebo. There is no evidence showing potential for abuse or dependence with ramelteon.

Sonata® (zaleplon) is used in the short-term management of insomnia. Zaleplon has been shown to decrease sleep latency with repeated use for periods up to 30 days in duration. Because of the drug's short half-life, clinical studies have focused on decreasing sleep latency. The drug has not been shown to substantially increase total sleep time or decrease the number of awakenings, and therefore appears to be most useful for sleep initiation disorders.

Pharmacy Coverage Guidelines

Note: Prescriptions that meet the initial step therapy requirements, will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, the prescription will be denied at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health 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 Commercial Formulary	Tufts Health Plan Generic Focused Formulary	Tufts Health Plan Medicare Preferred Formulary
Step-1			
zaleplon	Covered	Covered	Step Therapy criteria do not apply
zolpidem tartrate			
Step-2			
Lunesta®	Requires prior use of Step-1	Requires prior use of Step-1	Step Therapy criteria do not apply
Rozerem™			
Sonata®		Not Covered	
Not Covered (Step-3)			
Ambien®	Not Covered	Not Covered	Step Therapy criteria do not apply
Ambien CR™			

Step Therapy Coverage Criteria

The following stepped approach applies to insomnia treatments covered by Tufts Health Plan:

Step 1: Medications on Step-1 are covered without prior authorization.

Step 2: Tufts Health Plan may cover medications on Step-2 if the following criteria are met:

- The Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan or physician documented use of a Step-1 insomnia treatment within the previous 180 days.

OR

- The Member has had a previous paid claim under the prescription benefit administered by Tufts Health Plan or physician documented use, excluding the use of samples, of a Step-2 or Step-3 drug within the previous 180 days.

OR

- The Member has a physician documented contraindication or intolerance to zaleplon and zolpidem.

Not Covered (Step 3): Tufts Health Plan may cover drugs on Step-3 if the following criteria are met:

- A formulary exception request is submitted and approved by Tufts Health Plan for non-covered drugs. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs.

AND

- The Member has had previous paid claims under the prescription benefit administered by Tufts Health Plan or physician documented use, excluding the use of samples, of at least two covered alternative medications on Step-1, Step-2 or Step-3 within the previous 180 days.

Note: Formulary exception requests that meet the step therapy guidelines and are approved by Tufts Health Plan will adjudicate at the highest co-pay tier based on the Members pharmacy benefit.

Limitations

1. Medications on Step-2 or Step-3 are not covered unless the above step therapy criteria are met.
2. The following quantity limitations apply to any strength and combination of zaleplon, zolpidem tartrate, Lunesta, Rozerem, Sonata, Ambien and/or Ambien CR:
 - At retail pharmacy - 10 capsules/tablets per 30 days
 - At mail order pharmacy - 30 capsules/tablets per 90 days

Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Dispensing Limitations and submit a formulary exception request for those Members requiring higher quantities.

3. Exception requests for additional quantities of the drugs included in this program may be authorized in 12-month intervals.

Codes

None.

References

1. AHFS Drug Information. URL: <http://www.ashp.org>. Available from Internet. Accessed 2007 March 12.
2. Ambien® (zolpidem tartrate) [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC.; June 2006.
3. 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.
4. Emilien G, Salinas E for the Zaleplon Study Group. Zaleplon decreases sleep latency in outpatients after 4 weeks of treatment. *Eur J Neuropsychopharmacol*. 1998; 8(Suppl 2):S297.
5. Fullerton T, Frost M. Focus on zolpidem: a novel agent for the treatment of insomnia. *Hosp Formul*. 1992; 27:773-91.
6. Hurst M, Noble S. Zaleplon. *CNS Drugs*. 1999; 11:387-92.
7. Kryger MH, Steljes D, Pouliot Z et al. Subjective versus objective evaluation of hypnotic efficacy: experience with zolpidem. *Sleep*. 1991; 14:399-407.
8. Krystal AD, Walsh JK, Laska E et al. Sustained efficacy of eszopiclone over 6 months of nightly treatment: results of a randomized, double-blind, placebo-controlled study in adults with chronic insomnia. *Sleep*. 2003; 26:793-9.

9. Langtry HD, Benfield P. Zolpidem: a review of its pharmacodynamic and pharmacokinetic properties and therapeutic potential. *Drugs*. 1990; 40:291-313.
10. Lunesta[®] (eszopiclone) [package insert]. Marlborough, MA: Sepracor Inc.; April 2006.
11. Mack A, Salazar JO. Eszopiclone: a novel cyclopyrrolone with potential benefit in both transient and chronic insomnia. *Formulary*. 2003; 38:582-93.
12. Rozerem[™] (ramelteon) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; April 2006.
13. Sonata[®] (zaleplon) [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; March 2006.
14. Wagner J, Wagner ML, Hening WA. Beyond benzodiazepines: alternative pharmacologic agents for the treatment of insomnia. *Ann Pharmacotherapy*. 1998; 32:680-91.
15. 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.

Approval History

Reviewed by the Pharmacy and Therapeutics Committee on May 8, 2007.

Subsequent Endorsement Date(s) and Changes Made:

1. November 13, 2007: Added Tufts Health Plan Commercial Formulary to Step Therapy Program.
2. 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
3. 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.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). Tufts Health 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 Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan offerings unless otherwise noted in this policy or the Member's benefit document. However, for Tufts Health Plan Medicare Preferred Members, the Pharmacy Medical Necessity Guidelines only apply to Medicare Part D covered drugs. Tufts Medicare Preferred defers to Medicare coverage guidelines when reviewing Medicare Part B covered drugs. Medicare's national and local coverage determinations for Part B covered drugs can be accessed via the CMS coverage database at <http://www.cms.hhs.gov/mcd/search.asp>. Medicare general coverage guidelines are located in Chapter 15 of the Medicare Benefit Policy Manual, which can be accessed at <http://www.cms.hhs.gov/Manuals/IOM/list.asp>. Generally, Tufts Medicare Preferred requires prior authorization for the same drugs that require prior authorization for the fully insured Tufts Health

Plan offerings. Check the applicable formulary in the Pharmacy section of our Website at www.tuftshealthplan.com to determine if the drug requires you to get prior authorization. This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

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.