

Criteria for Nonformulary Use of Eszopiclone (Lunesta®)

VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient situation.

Exclusion Criteria	Comments
<p>Patient with symptoms of insomnia associated with one or more of the following conditions: *</p> <ul style="list-style-type: none"> <input type="checkbox"/> 1. A psychiatric and/or medical illness without any, or an inadequate trial, of other formulary alternatives or nonpharmacological interventions deemed appropriate to use (e.g., sedating antidepressants, benzodiazepines). <input type="checkbox"/> 2. Pregnancy <input type="checkbox"/> 3. Active alcohol/illicit drug use/abuse/dependence <input type="checkbox"/> 4. Concurrent use with any other sedative hypnotics or other medications including over-the counter analgesics that contain caffeine or herbal supplements (e.g., melatonin, St. John's Wort) for the treatment of symptoms related to insomnia. <input type="checkbox"/> 5. No attempts or consideration has been made and documented to discontinue or adjust any medications/substances known to affect sleep 	<p><i>If any of the boxes are checked, patient is not a candidate to receive eszopiclone.</i></p> <p><i>If none of the boxes is checked, proceed to the Inclusion Criteria for Therapy section below.</i></p> <p>*Part of the evaluation of insomnia should include assessment of other drugs or conditions (e.g. chemical dependence, sleep apnea) that may be interfering with sleep.</p>
<p>Inclusion Criteria for Short-Term Therapy for Insomnia</p> <ul style="list-style-type: none"> <input type="checkbox"/> 1. Patient with acute (short-term) insomnia defined as periods of sleep difficulty lasting less than one month and basic sleep interventions (e.g., sleep hygiene, relaxation training) have failed to improve sleep difficulties <input type="checkbox"/> 2. Patient with acute (short-term) insomnia until treatment associated with any underlying psychiatric and/or medical illnesses takes affect (e.g., depression) <input type="checkbox"/> 3. Intolerance/contraindication/documentated failure to other appropriate formulary treatment alternatives (e.g., sedating antidepressants, benzodiazepines) 	<p>Box #1 AND at least one of the two remaining boxes needs to be checked for patient to be eligible to receive eszopiclone for the short-term management of insomnia.</p> <p><i>Patient Resources for Basic Hygiene Education</i> http://www.womenshealth.gov/faq/insomnia.htm#5 http://www.aasmnet.org/FactSheet.aspx http://www.sleepfoundation.org/ <i>Example of a sleep diary:</i> http://www.nhlbi.nih.gov/health/prof/sleep/insom_pc.pdf <i>Professional Education:</i> http://www.sleepfoundation.org/ http://www.ahrq.gov/clinic/epcsums/insomsum.htm</p> <p>Please note: Hypnotics should generally be limited to 7-10 days of use for short-term therapy. The failure of symptoms of insomnia to improve after 7-10 days of treatment may indicate the presence of an underlying condition that needs to be evaluated.</p> <p>Please note: Published trials of eszopiclone primarily in the elderly population (≥ 65 years of age) have not been conducted longer than 2 consecutive weeks.</p>
<p>Inclusion Criteria for Long-Term Therapy for Insomnia</p> <ul style="list-style-type: none"> <input type="checkbox"/> 1. Patient with DSM-IV criteria for chronic primary insomnia (≤ 6.5 hours of sleep/night and requires > 30 min to fall asleep each night for at least 1 month) AND basic sleep interventions (e.g., sleep hygiene, relaxation training) have failed to improve sleep difficulties and treatment such as cognitive behavioral therapy (e.g., stimulus control, sleep restriction, cognitive therapy, and sleep education), IF AVAILABLE and FEASIBLE, has not been successful. <input type="checkbox"/> 2. Intolerance/contraindication/documentated failure to other appropriate formulary treatment alternatives (e.g., sedating antidepressants and benzodiazepines) <p>For patients requiring long-term therapy, evaluation by a sleep specialist (e.g., neurologists, pulmonologists, psychiatrists, medical practitioners board certified in sleep medicine) or a behavioral therapist that are experienced in sleep intervention techniques is recommended.</p>	<p>Both boxes need to be checked for patient to be eligible to receive eszopiclone for long-term management of insomnia.</p> <p>Please note: Published trials of eszopiclone primarily in the elderly population (≥ 65 years of age) have not been conducted longer than 2 consecutive weeks.</p> <p>It is strongly recommended that patients be evaluated within 3-5 weeks of the initial Rx to document any improvement in the symptoms related to insomnia. Patients should be re-evaluated regularly and adjunctive behavioral modification therapy be continued. If not done, reconsideration should be made whether Rx for eszopiclone should be continued.</p>

The drug monograph for eszopiclone is located at <http://www.pbm.va.gov/monograph/7edt7Eszopiclone.pdf>

Approved by Physician: _____ Date/time: _____
 Patient name (last 4): _____ Reviewer: _____
 approved _____