Pharmacy Medical Necessity Guidelines: Insomnia Treatments

Effective: January 1, 2019

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
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<table>
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<tr>
<th>Not Covered</th>
<th>Type of Review – Clinical Review</th>
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<thead>
<tr>
<th>Pharmacy (RX) or Medical (MED) Benefit</th>
<th>Department to Review</th>
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</thead>
<tbody>
<tr>
<td>RX</td>
<td>RXUM</td>
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</tbody>
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Fax Numbers:
RXUM: 617.673.0988

This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RIté Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

**Note:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Step Therapy Criteria. 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 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.

**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:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Tufts Health Plan Large Group Plans</th>
<th>Tufts Health Plan Small Group and Individual Plans</th>
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</thead>
<tbody>
<tr>
<td><strong>Step-1</strong></td>
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<tr>
<td>zaleplon</td>
<td>Covered</td>
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<tr>
<td>zolpidem tartrate</td>
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<td></td>
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<tr>
<td>eszopiclone</td>
<td></td>
<td></td>
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<tr>
<td><strong>Step-2</strong></td>
<td></td>
<td></td>
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<tr>
<td>Rozerem™</td>
<td>Requires prior use of a drug on Step-1 or Step-2</td>
<td>Requires prior use of a drug on Step-1 or Step-2</td>
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<tr>
<td>zolpidem tartrate CR</td>
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<tr>
<td>Zolpidem tartrate sublingual</td>
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<tr>
<td><strong>Step-3</strong></td>
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</tr>
<tr>
<td>Belsomra®</td>
<td>Requires prior use of a drug on Step-2 or Step-3</td>
<td>Requires prior use of a drug on Step-2 or Step-3</td>
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<tr>
<td>Zolpimist™</td>
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**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:
- 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:
- 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:
- The Member has had previous trial of a Step-1 or Step-2 medication as evidenced by physician documented use, excluding the use of samples
  
  **OR**

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

**Step 3:** The plan may cover medications on Step-3 if the following criteria are met:
- The Member has had a trial of a Step-2 or Step-3 medication as evidenced by physician's documented use, excluding the use of samples
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, excluding the use of samples.

LIMITATIONS
1. Medications on Step-2 and Step-3 are not covered unless the above step therapy criteria are met.
2. Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
3. The brand-name products Ambien, Ambien CR, Edluar, Sonata, Lunesta and Intermezzo 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, 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
**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.
- 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.
- 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.

**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. They are used in conjunction with a Member’s benefit document and in coordination with the...
Member’s physician(s). 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.

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 CareLink℠ 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.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.