HYPNOTIC UTILIZATION MANAGEMENT CRITERIA

**DRUG CLASS:** Central Nervous System (CNS) depressants

**BRAND NAME (Generic):** Zaleplon (Sonata®), Zolpidem (Ambien®, Ambien CR®), Eszopiclone (Lunesta™), Ramelteon (Rozerem™)

**FDA INDICATIONS:** Eszopiclone, ramelteon, zaleplon and zolpidem are indicated for the treatment for insomnia (the inability to get the amount or quality of sleep necessary for optimal functioning and well being). Hypnotics should generally be limited to 7-10 days of use, and re-evaluation of the patient is recommended if they are to be taken for a longer period.

**QUANTITY LIMITATIONS (QL) CRITERIA:**

<table>
<thead>
<tr>
<th></th>
<th>SHORT TERM:</th>
<th>EXTENDED SUPPLY:</th>
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<tbody>
<tr>
<td>Zaleplon (Sonata®)</td>
<td>15 units 30 day supply</td>
<td>45 units 90 day supply</td>
</tr>
<tr>
<td>Zolpidem (Ambien®, Ambien CR®)</td>
<td>15 units 30 day supply</td>
<td>45 units 90 day supply</td>
</tr>
<tr>
<td>Eszopiclone (Lunesta™)</td>
<td>15 units 30 day supply</td>
<td>45 units 90 day supply</td>
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<tr>
<td>Ramelteon (Rozerem™)</td>
<td>15 units 30 day supply</td>
<td>45 units 90 day supply</td>
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If patient is requiring amounts in excess of these numbers, please follow the Criteria for Exceeding QL developed for zaleplon, zolpidem, eszopiclone, and ramelteon.

**RATIONALE:**

- Most cases of insomnia are transient (short-term) which may last from a few days to 3 weeks. In transient insomnia 7-10 nights of hypnotic drug therapy may be sufficient and treatment generally is not needed for greater than 3 weeks.
- Patients with chronic persistent insomnia, which can last for months or years, may experience insomnia up to 4 nights per week. Some chronic persistent insomnia patients may experience nightly episodes of insomnia that requires nightly therapy.
- Chronic insomnia is most commonly associated with an underlying condition.
- Significant outcomes studies have not been conducted to establish the impact of hypnotic use on overall health and well-being.

**BENEFIT DESIGN:**

This prescription drug benefit provides coverage immediately (without generating a coverage review process) for a drug quantity sufficient for 15 treatment nights of therapy in any 30 day period (45 treatment nights of therapy in any 90 day period).

Requests for coverage of a greater drug quantity (i.e., > 15 units in any 30 day period, > 45 units in any 90 day period) are determined through the coverage authorization process below.
**CRITERIA FOR EXCEEDING QL:**
Coverage for doses above 15 units/30 day supply or 45 units/90 day supply is provided for situations in which the prescriber supplies documentation of the following:

- Patient requires nightly therapy for the treatment of chronic persistent insomnia (insomnia that occurs greater than 4 nights weekly for greater than 3 months in duration)
- Patient has failed sleep hygiene
- Patient has avoided stimulants
- **Underlying psychiatric and/or medical conditions causing insomnia have been evaluated and treated.**

**WARNINGS:**

**ADEQUATE PATIENT EVALUATION:** Since sleep disturbances may be manifestations of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after careful evaluation of the patient. The failure of insomnia to remit after 7-10 days of therapy may indicate the presence of an underlying psychiatric and/or medical condition requiring evaluation.

**REFERENCES:**
17. Sanofi-Synthelabo. Ambien Medical Information. 1-800-446-6267.
18. Sepracor. Lunesta Medical Information. 1-800-739-0565.