# PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS</th>
<th>INSOMNIA AGENTS (NONBENZODIAZEPINE AGENTS)</th>
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</thead>
<tbody>
<tr>
<td>BRAND NAME</td>
<td>AMBIEN (zolpidem)</td>
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<tr>
<td></td>
<td>AMBIEN CR (zolpidem extended-release)</td>
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<tr>
<td></td>
<td>LUNESTA (eszopiclone)</td>
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<td></td>
<td>ROZEREM (ramelteon)</td>
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<td>SONATA (zaleplon)</td>
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**Status:** CVS Caremark Criteria  
**Type:** Post Limit Prior Authorization

## POLICY

### FDA-APPROVED INDICATIONS

**Ambien**
Ambien is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Ambien has been shown to decrease sleep latency 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**
Ambien CR 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 3 weeks (using polysomnography measurement up to 2 weeks in both adult and elderly patients) and 24 weeks (using patient-reported assessment in adult patients only) in duration.

**Lunesta**
Lunesta is indicated for the treatment of insomnia. In controlled outpatient and sleep laboratory studies, Lunesta 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**
Rozerem is indicated for the treatment of insomnia characterized by difficulty with sleep onset. The clinical trials performed in support of efficacy were up to 6 months in duration. The final formal assessments of sleep latency were performed after 2 days of treatment during the crossover study (elderly only), at 5 weeks in the 6 week studies (adults and elderly), and at the end of the 6 month study (adults and elderly).
Sonata
Sonata is indicated for the short-term treatment of insomnia. Sonata 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.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The drug is being prescribed for insomnia
- Potential causes of sleep disturbances have been addressed (e.g., inappropriate sleep hygiene and sleep environment issues or treatable medical/psychological causes of chronic insomnia)
- The patient does not require MORE than 60 capsules per month of Sonata (zaleplon), or 30 tablets per month of Ambien (zolpidem), Ambien CR (zolpidem extended-release), Lunesta (eszopiclone), or Rozerem (ramelteon)

Quantity Limits may apply.

REFERENCES