

# QUANTITY LIMIT CRITERIA

<b>DRUG CLASS</b>	<b>INSOMNIA AGENTS**</b>
<b>BRAND NAME (generic)</b>	<b>AMBIEN (zolpidem)</b>
	<b>AMBIEN CR (zolpidem extended-release)</b>
	<b>DORAL (quazepam)</b>
	<b>(estazolam)</b>
	<b>(flurazepam)</b>
	<b>HALCION (triazolam)</b>
	<b>LUNESTA (eszopiclone)</b>
	<b>RESTORIL (temazepam)</b>
	<b>ROZEREM (ramelteon)</b>
	<b>SONATA (zaleplon)</b>

**Status: CVS Caremark Criteria**

**Type: Quantity Limit**

*\*\* Edluar, Intermezzo, ZolpiMist, Belsomra and Dayvigo are not included in these criteria. Refer to Insomnia (Edluar, Intermezzo, ZolpiMist) or Insomnia (Belsomra, Dayvigo) Prior Authorization criteria.*

## POLICY

### FDA-APPROVED INDICATIONS

#### **Ambien**

Ambien (zolpidem tartrate) 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 4–5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.

### **Ambien CR**

Ambien CR (zolpidem tartrate extended-release tablets) 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.

### **Doral**

Doral is indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. The effectiveness of Doral has been established in placebo-controlled clinical studies of 5 nights duration in acute and chronic insomnia.

The sustained effectiveness of Doral has been established in chronic insomnia in a sleep lab (polysomnographic) study of 28 nights duration. Because insomnia is often transient and intermittent, the prolonged administration of Doral Tablets is generally not necessary or recommended. Since insomnia may be a symptom of several other disorders, the possibility that the complaint may be related to a condition for which there is a more specific treatment should be considered.

### **Estazolam**

Estazolam tablets, USP are indicated for the short-term management of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. Both outpatient studies and a sleep laboratory study have shown that estazolam administered at bedtime improved sleep induction and sleep maintenance.

Because insomnia is often transient and intermittent, the prolonged administration of estazolam is generally neither necessary nor recommended. Since insomnia may be a symptom of several other disorders, the possibility that the complaint may be related to a condition for which there is a more specific treatment should be considered.

There is evidence to support the ability of estazolam to enhance the duration and quality of sleep for intervals up to 12 weeks.

### **Flurazepam**

Flurazepam hydrochloride capsules are indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings.

Since insomnia is often transient and intermittent, short-term use is usually sufficient. Prolonged use of hypnotics is usually not indicated and should only be undertaken concomitantly with appropriate evaluation of the patient.

### **Halcion**

Halcion is indicated for the short-term treatment of insomnia (generally 7 to 10 days) in adults.

### **Lunesta**

Lunesta (eszopiclone) 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 6 months in duration. The final formal assessments of sleep latency and maintenance were performed at 4 weeks in the 6-week study (adults only), at the end of both 2-week studies (elderly only) and at the end of the 6-month study (adults only).

### **Restoril**

Restoril (temazepam) is indicated for the short-term treatment of insomnia (generally 7 to 10 days).

For patients with short-term insomnia, instructions in the prescription should indicate that Restoril (temazepam) should be used for short periods of time (7 to 10 days).

The clinical trials performed in support of efficacy were 2 weeks in duration with the final formal assessment of sleep latency performed at the end of treatment.

### **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 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 six-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 5 weeks in duration. The final formal assessments of sleep latency were performed at the end of treatment.

#### **LIMIT CRITERIA**

**Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.**

<b>Drug</b>	<b>1 Month Limit*</b>	<b>3 Month Limit*</b>
Ambien all strengths (zolpidem)	15 tablets/25 days	45 tablets/75 days
Ambien CR all strengths (zolpidem extended-release)	15 tablets/25 days	45 tablets/75 days
Doral all strengths (quazepam)	15 tablets/25 days	45 tablets/75 days
estazolam all strengths	15 tablets/25 days	45 tablets/75 days
flurazepam all strengths	15 capsules/25 days	45 capsules/75 days
Halcion all strengths (triazolam)	10 tablets/25 days	30 tablets/75 days
Lunesta all strengths (eszopiclone)	15 tablets/25 days	45 tablets/75 days
Restoril all strengths (temazepam)	15 capsules/25 days	45 capsules/75 days
Rozerem all strengths (ramelteon)	15 tablets/25 days	45 tablets/75 days
Sonata all strengths (zaleplon)	15 capsules /25 days	45 capsules /75 days

\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

#### **REFERENCES**

1. Ambien [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; September 2020.
2. Ambien CR [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; September 2020.
3. Doral [package insert]. Atlanta, GA: Galt Pharmaceuticals LLC; October 2020.
4. Estazolam [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; January 2021.
5. Flurazepam [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; December 2018.
6. Halcion [package insert]. New York, NY: Pharmacia and Upjohn Company; February 2021.
7. Lunesta [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; August 2019.
8. Restoril [package insert]. Webster Groves, MO: SpecGx LLC; February 2021.
9. Rozerem [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; December 2018.
10. Sonata [package insert]. Bristol, TN: King Pharmaceuticals Inc.; December 2019.
11. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed February 2021.
12. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed February 2021.
13. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: An American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2017;13(2):307-349.

14. Qaseem A, Kansagara D, Forcica MA, Cooke M, Denberg TD, Management of chronic insomnia disorder in adults: A clinical practice guideline from the American College of Physicians. *Ann Intern Med*. Epub, 2016. 165(2):125-33. doi: 10.7326/M15-2175. Epub 2016 May 3.
15. Schutte-Rodin S, Broch L, Buysse D, Dorsey C, Sateia M. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med* 2008; 4(5):487-504.