

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

## Non-Preferred Sedative Hypnotic Agents for Insomnia

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Comments	Quantity Limit
zaleplon (generic Sonata) 5mg, 10mg capsules	Preferred	May be subject to quantity limits
zolpidem (generic Ambien) 5mg, 10mg tablets		
Ambien (brand) 5mg, 10mg tablets	Non-Preferred	
Ambien CR (brand and generic) 6.25mg, 12.5mg extended-release tablets		
Belsomra 5mg, 10mg, 15mg 20mg tablets		
Dayvigo 5mg, 10mg tablets		
Edluar 5mg, 10mg sublingual tablets		
Intermezzo (brand and generic) 1.75mg, 3.5mg sublingual tablets		
Lunesta (brand and generic) 1mg, 2mg, 3mg tablets		
Rozerem 8mg tablets		
Silenor 3mg, 6mg tablets		
Sonata (brand) 5mg, 10mg capsules		
Zolpimist 5mg/actuation solution		

CRX-ALL-0557-20

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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## **APPROVAL CRITERIA**

Requests for a non-preferred sedative hypnotic agent for insomnia may be approved if the following criteria are met:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to two preferred agents;

Preferred agents: zaleplon (generic Sonata), zolpidem (generic Ambien).

Non-preferred agents: Ambien (brand), Ambien CR (brand and generic), Belsomra, Dayvigo, Edluar, Intermezzo (brand and generic), Lunesta (brand and generic), Rozerem, Silenor, Sonata (brand), Zolpimist.

### **OR**

- II. Rozerem (ramelteon) and Silenor (doxepin) may be approved for individuals with a history of substance abuse disorders (AASM 2008, SAMHSA 2014).
- III. Requests for Lunesta (brand and generic) 3mg must also meet the following criteria, in addition to I. or II. above:
  - A. Individual is 64 years of age or younger.

### **Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 24, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

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5. SAMHSA (Substance Abuse and Mental Health Services Administration) In Brief. Treating sleep problems of people in recovery from substance use disorders. Fall 2014; 8 (2): 1-8. Available from: <https://store.samhsa.gov/shin/content/SMA14-4859/SMA14-4859.pdf>. Accessed March 24, 2020.
6. Sateia MJ, Buysse DJ, Krystal AD, et.al. 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.
7. 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.

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