

## Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

<b>Guideline Name</b>	Sedative Hypnotic Agents
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Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, the below prior authorization criteria will apply. See background section for details.

### 1 . Criteria

Product Name: Edluar, Rozerem, Belsomra, Silenor, Zolpimist	
Approval Length	12 Month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization/Step Therapy, Non-Formulary
<p><b>Approval Criteria</b></p> <p>1 - Both of the following:</p> <p>1.1 Patient lives in Rhode Island or the prescribing physician's office is located in Rhode Island*</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2 The requested medication is on formulary</p> <p style="text-align: center;"><b>OR</b></p> <p>2 - All of the following:</p> <p>2.1 Diagnosis of insomnia</p> <p style="text-align: center;"><b>AND</b></p> <p>2.2 One of the following:</p> <p>2.2.1 Patient has tried and failed therapy with generic zolpidem/CR, zaleplon, or eszopiclone</p> <p style="text-align: center;"><b>OR</b></p> <p>2.2.2 Patient is currently taking the requested medication and is responding well</p>	
Notes	*Note: Requests for formulary medications will be approved for 12 months without meeting any additional criteria if the patient is living in Rhode Island or the prescribing physician's office is located in Rhode Island.

Product Name: Brand Ambien, Brand Ambien CR, Brand Lunesta, Brand Intermezzo	
Approval Length	12 Month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non-Formulary
<p><b>Approval Criteria</b></p> <p>1 - All of the following:</p> <p>1.1 Diagnosis of insomnia</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2 Both of the following:</p> <p>1.2.1 Patient has tried and failed therapy with the generic product of the requested drug</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2.2 Patient has tried and failed therapy with one additional product within the same therapeutic class [e.g., Ambien (zolpidem), Lunesta (eszopiclone), Rozerem (ramelteon), Silenor (doxepin), zaleplon, Belsomra (suvorexant)]</p>	

Product Name: Edluar, Rozerem, Belsomra, Silenor, Zolpimist, Brand Ambien, Brand Ambien CR, Brand Lunesta, Brand Intermezzo	
Approval Length	12 Month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization/Step Therapy, Non-Formulary
<p><b>Approval Criteria</b></p> <p>1 - Both of the following:</p> <p>1.1 Patient lives in Rhode Island or the prescribing physician's office is located in Rhode Island*</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2 The requested medication is on formulary</p> <p style="text-align: center;"><b>OR</b></p> <p>2 - All of the following:</p> <p>2.1 Diagnosis of insomnia</p>	

**AND**

**2.2 Patient has experienced improvement while on therapy**

Notes

\*Note: Requests for formulary medications will be approved for 12 months without meeting any additional criteria if the patient is living in Rhode Island or the prescribing physician's office is located in Rhode Island.

## 2 . Background

### Benefit/Coverage/Program Information

**NOTE: Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then the prescription will deny at point of service with a message indicating that prior authorization (PA) is required.**

Members who do not meet the step therapy criteria at point of service will need to submit a request for clinical review. First level drug therapy required include the following:

- Generic zolpidem and zolpidem controlled release;
- Generic zaleplon;
- Generic eszopiclone;
- Doxepin is considered first line for Silenor only, not other sleep agents;
- Lookback is 120 days.

#### **RATIONALE**

To discourage first line use with brand name sedative hypnotics due to the availability of generic zolpidem, zaleplon, and eszopiclone.

#### **FDA APPROVED INDICATIONS**

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.

Ambien CR (zolpidem tartrate controlled-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).

Belsomra (suvorexant) is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

Edluar (zolpidem tartrate sublingual) is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

Intermezzo (zolpidem tartrate sublingual) is indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. (Limitation of Use: Not indicated for the treatment of middle-of-the-night awakening when the patient has fewer than 4 hours of bedtime remaining before the planned time of

waking).

Lunesta (eszopiclone) is indicated for the treatment of insomnia.

Rozerem (ramelteon) is indicated for the treatment of insomnia characterized by difficulty with sleep onset.

Silenor (doxepin) is indicated for the treatment of insomnia characterized by difficulties with sleep maintenance.

Zaleplon is indicated for the short term treatment of insomnia.

Zolpimist (zolpidem tartrate oral spray) is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

### REFERENCES

- Ambien (zolpidem tartrate tablet) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; August 2019.
- Ambien CR (zolpidem tartrate extended-release tablet) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; August 2019.
- Lunesta (eszopiclone) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; August 2019.
- Rozerem (ramelteon) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals; December 2018.
- Zaleplon Product Information. Teva Pharmaceuticals USA, Inc. August 2015.
- Edluar (zolpidem tartrate sublingual tablet) [prescribing information]. Somerset, NJ: Meda Pharmaceuticals; August 2019.
- Intermezzo (zolpidem tartrate tablet) [prescribing information]. Stamford, CT: Purdue Pharma LP; August 2019.
- Silenor (doxepin) [prescribing information]. San Diego, CA: Somaxon Pharmaceuticals Inc; March 2010.
- Zolpimist oral spray (zolpidem tartrate) [prescribing information]. Englewood, CO: Aytu BioScience, Inc.; February 2019.
- Belsomra (suvorexant) [prescribing information]. Whitehouse Station, NJ: Merck, Sharpe & Dohme; July 2018.

Created: 05/22/07
Revised: 5/20/20 (clarified guideline type to include Step Therapy)
P&T Approval: 12/02/19
Effective: 6/1/20