Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

Guideline Name	**Sedative Hypnotic Agents**: Ambien (zolpidem), Ambien CR (zolpidem controlled-release), Belsomra (suvorexant), Edular (zolpidem sublingual), Intermezzo (zolpidem sublingual), Lunesta (eszopiclone), Rozerem (ramelteon), Silenor (doxepin tablet), Zolpimist (zolpidem oral spray)

1 . Criteria

Product Name: Edluar, Belsomra, generic doxepin tablet, generic ramelteon, Zolpimist	
Approval Length	12 Month(s)^
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization/Step Therapy, Non-Formulary

Approval Criteria

1 - Both of the following:

1.1 Patient lives in Rhode Island or the prescribing physician's office is located in Rhode Island*

AND

1.2 The requested medication is on formulary

OR

2 - All of the following:

2.1 Diagnosis of insomnia

AND

2.2 One of the following:

2.2.1 Patient has tried and failed therapy with generic zolpidem/CR, zaleplon, or eszopiclone

OR

2.2.2 Patient is currently taking the requested medication and is responding well

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. ^Please approve generic doxepin tablets at GPI-12 and MSC=Y. Please approve generic ramelteon at MSC=Y.

Product Name: Brand Ambien, Brand Ambien CR, Brand Lunesta, Brand Intermezzo, Brand Rozerem, Brand Silenor	
Approval Length	12 Month(s)^
Therapy Stage	Initial Authorization
Guideline Type	Non-Formulary

Approval Criteria

1 - All of the following:

1.1 Diagnosis of insomnia

AND

1.2 Both of the following:

1.2.1 Patient has tried and failed therapy with the generic product of the requested drug

AND

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)]

Notes	^Please approve Brand Silenor at GPI-12.

Product Name: Edluar, Belsomra, Zolpimist, Brand Ambien, Brand Ambien CR, Brand Lunesta, Brand Intermezzo, Brand Rozerem, generic ramelteon, Brand Silenor, generic doxepin tablet,	
Approval Length	12 Month(s)^
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization/Step Therapy, Non-Formulary

Approval Criteria

1 - Both of the following:

1.1 Patient lives in Rhode Island or the prescribing physician's office is located in Rhode Island*

AND

1.2 The requested medication is on formulary

OR

2 - All of the following:

2.1 Diagnosis of insomnia

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. ^Please approve Brand Silenor and generic doxepin tablets at GPI-12. Please approve generic formulations as MSC=Y.

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; • Generic doxepin capsule/oral concentrate is considered first line for doxepin tablets only, not other sleep agents; • Lookback is 180 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 capsules [prescribing information]. East Windsor, NJ: Aurobindo Pharma USA, Inc; September 2019.
- 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]. Morristown, NJ: Currax Pharmaceuticals, LLC; August 2019.
- Zolpimist oral spray (zolpidem tartrate) [prescribing information]. Englewood, CO: Aytu BioScience, Inc.; February 2019.
- Belsomra (suvorexant) [prescribing information]. Whitehouse Station, NJ: Merck, Sharpe & Dohme Corp; March 2020.

Created: 05/22/07
Revised: • Annual review (effective: 1/1/20) • 5/20/20 - Clarified guideline type to include Step Therapy (effective: 6/1/20) • 9/20/20 - Annual review: background updates; moved Brand Rozerem and Brand Silenor to require generic and 1 other trial section; increased ST lookback from 120 days to 180 days
P&T Approval: 12/7/20
Effective: 1/1/21