HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

SEDATIVE HYPNOTIC AGENTS

Generic	Brand	HICL	GCN	Exception/Other
ZOLPIDEM TARTRATE	AMBIEN AMBIEN CR EDLUAR INTERMEZZO ZOLPIMIST	07842		GENERIC IS UNRESTRICTED
ESZOPICLONE	LUNESTA	26791		GENERIC IS UNRESTRICTED
RAMELTEON	ROZEREM	33126		
DOXEPIN HCL	SILENOR		28914, 28915	
ZALEPLON	SONATA	20347		GENERIC IS UNRESTRICTED
SUVOREXANT	BELSOMRA	41333		

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 Medication Request Form (MRF) to MedImpact for clinical review. First level drug therapy required include the following:

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

CUSTOMER SERVICE REPRESENTATIVE (CSR)
PA COORDINATOR (PAC)

This is a Rhode Island (RI) member or prescriber determination for behavioral health and substance abuse requests:

1. Does the member live in Rhode Island **or** is the prescribing physician's office located in Rhode Island?

   If yes, continue to #2.
   If no, continue to review using the clinical determination criteria below. For Customer Service, all other requests require a Medication Request Form (MRF) be submitted for review.

2. Is the requested medication non-formulary?

   If yes, continue to review using the clinical determination criteria below. For Customer Service, all other requests require a Medication Request Form (MRF) be submitted for review.
   If no, **approve for 12 months by HICL.**

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CLINICAL DETERMINATION CRITERIA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of insomnia?

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Sedative Hypnotic Agents guideline, this medication is only covered when prescribed for insomnia. Your provider did not indicate that you are being treated for this condition and therefore your request was not approved.

2. Is the request for a multisource brand?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient tried and failed therapy with the generic product of the requested drug within the previous year **AND** at least one additional product within the same therapeutic class [e.g., Ambien (zolpidem), Lunesta (eszopiclone), Rozerem (ramelteon), Silenor (doxepin, Sonata (zaleplon), Belsomra (suvorexant)]?

   If yes, continue to #6.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Sedative Hypnotic Agents guideline, a trial with the requested drug's generic equivalent **[(generic name)]** within the past year AND at least one formulary alternative, such as **[select as appropriate: zolpidem, eszopiclone, Rozerem, zaleplon]** is required prior to approving coverage of the requested medication. Your provider did not indicate that you have tried **[the generic within the past year and/or an alternative medication]** and therefore your request was not approved.

4. Has the patient tried and failed therapy with a 7-day trial of generic zolpidem/CR, zaleplon, or eszopiclone within the previous 120 days?

   If yes, continue to #6.
   If no, continue to #5.

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SEDATIVE HYPNOTIC AGENTS

INITIAL CRITERIA (CONTINUED)

5. Is the patient currently taking the requested medication and responding well?

   If yes, continue to #6.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Sedative Hypnotic Agents guideline, your plan requires a 7-day trial of generic zaleplon, generic zolpidem/CR, or generic eszopiclone, within the previous 120 days, prior to approving coverage for the requested medication. Your provider did not indicate that you have been treated with generic zaleplon, generic zolpidem/CR, or generic eszopiclone within the previous 120 days, and therefore your request was not approved.

6. **Approve for 12 months by HICL.**
   Please use status code #057 (#056 for Belsomra [The quantity limit is hard-coded]) and the approval text provided.

   Requests for products on formulary with a restriction,
   APPROVAL TEXT: Your request for _____ has been approved for a 12-month period.

   APPROVAL TEXT (Belsomra only): Your request for Belsomra has been approved for a 12-month period with a quantity limit of one tablet per day.

   Requests for products not on formulary,
   APPROVAL TEXT: Your request for **[REQUESTED DRUG]** has been approved for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of insomnia?

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Sedative Hypnotic Agents guideline, this medication is only covered when prescribed for insomnia. Your provider did not indicate that you are being treated for this condition and therefore your request was not approved.

2. Has the patient experienced improvement while on therapy?

   If yes, continue to #3.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Sedative Hypnotic Agents guideline, authorization for renewal requires documentation of improvement of symptoms while on therapy with **[requested drug]**. Your provider did not indicate that your symptoms have improved with **[requested drug]** therapy and therefore your request was not approved.

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SEDATIVE HYPNOTIC AGENTS

RENEWAL CRITERIA (CONTINUED)

3. **Approve for 12 months by HICL.** Please use status code #057 (#056 for Belsomra [The quantity limit is hard-coded]) and the approval text provided.

   Requests for products on formulary with a restriction,
   APPROVAL TEXT: Your request for **[REQUESTED DRUG]** has been approved for a 12-month period.

   APPROVAL TEXT (Belsomra only): Your request for Belsomra has been approved for a 12-month period with a quantity limit of one tablet per day.

   Requests for products not on formulary,
   APPROVAL TEXT: Your request for **[REQUESTED DRUG]** has been approved for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

RATIONALE
To discourage first line use with brand name sedative hypnotics due to the availability of generic Ambien/CR, generic Sonata, and generic Lunesta.

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.

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SEDATIVE HYPNOTIC AGENTS

FDA APPROVED INDICATIONS (CONTINUED)

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

Sonata (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 Product Information. Sanofi Aventis US. October 2014.
- Ambien CR Product Information. Sanofi Aventis US. October 2014.
- Lunesta Product Information. Sepracor, Inc. May 2014.
- Rozerem Product Information. Takeda Pharmaceuticals North America. November 2010.
- Sonata Product Information. Pfizer Pharmaceuticals, Inc. May 2013.
- Edluar Product Information. Meda. October 2014.
- Intermezzo Product Information. Purdue Pharma. July 2015.
- Silenor Product Information. Prenix. March 2010.
- Zolpimist Product Information. NovaDel Pharma Inc. May 2013.
- Belsomra Product Information. Merck and Co., Inc. May 2016.

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