PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**INSOMNIA AGENTS**
BRAND NAME* (generic)	**BELSOMRA (suvorexant)** **DAYVIGO (lemborexant)**
Status: CVS Caremark Criteria	
Type: Initial Prior Authorization	***Ref # 1177-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Belsomra

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

Dayvigo

Dayvigo (lemborexant) is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance
  AND
- Potential factors contributing to sleep disturbances have been addressed or are currently being addressed (e.g., inappropriate sleep hygiene and sleep environment issues) as well as treatable medical/psychiatric disorders that are co-morbid with insomnia
  AND
- If the patient is less than 65 years of age:
  - The patient experienced an inadequate treatment response to any of the following: A) a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem), B) a benzodiazepine (e.g., temazepam)
    OR
  - The patient experienced an intolerance to any of the following A) a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem), B) a benzodiazepine (e.g., temazepam)
    OR
  - The patient has a contraindication that would prohibit a trial of ALL of the following A) a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem), B) a benzodiazepine (e.g., temazepam)

Quantity Limits apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Belsomra (suvorexant) and Dayvigo (lemborexant) are indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.[1, 2]

Because sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment should be initiated only after a careful evaluation of the patient.[1, 2] Per clinical practice guidelines, insomnia is defined as dissatisfaction with sleep quantity or quality and is associated with difficulty initiating or maintaining sleep and early morning waking with inability to return to sleep. Insomnia disorder is identified as chronic when symptoms cause clinically significant functional distress or impairment, be present at least 3 months at a frequency of at least 3 nights per week, and not be linked to other sleep, medical, or mental disorders.[5,6] General treatment measures for insomnia include the treatment of comorbid medical and psychiatric conditions, modifying sleep-interfering medications and substances, and optimizing the sleep environment.[5] The American College of Physicians recommends that all adult patients receive cognitive behavioral therapy for insomnia (CBT-I) as the initial treatment for chronic insomnia disorder. CBT-I consists of a combination of cognitive therapy, behavioral interventions (such as sleep restriction and stimulus control), and educational interventions (such as sleep hygiene).[6] According to the American Academy of Sleep Medicine (AASM), despite the clearly favorable benefit to risk ratio of CBT-I, not all patients with an insomnia disorder can and will derive benefit from this treatment alone. Thus, pharmacotherapy, alone or in combination with CBT-I, must continue to be considered a part of the therapeutic armamentarium.[5]

The AASM clinical practice guideline makes recommendations for treating sleep onset insomnia and sleep maintenance insomnia. Recommendations are not made for specific drugs over other drugs, rather the recommendations are made for treatment with a specific drug versus no treatment. The classes of drugs that received favorable recommendations include: orexin receptor agonists (suvorexant), non-benzodiazepine sedative hypnotics (eszopiclone, zaleplon, zolpidem), benzodiazepines (temazepam), melatonin agonists (ramelteon), and heterocyclics (Silenor [doxepin 3 mg, 6 mg]). Suvorexant is recommended for treating sleep maintenance insomnia as is Silenor. Ramelteon, and zaleplon are recommended for the treatment of sleep onset insomnia. The guidelines recommend temazepam, eszopiclone, and zolpidem for the treatment of both sleep maintenance insomnia as well as sleep onset insomnia.[5] Therefore, the patient should have an inadequate treatment response, intolerance or contraindication to a generic non-benzodiazepine sedative hypnotic (e.g., eszopiclone, zaleplon, zolpidem) or a benzodiazepine (e.g., temazepam).

The intention of the American Geriatrics Society (AGS) Beers Criteria is to improve medication selection; educate clinicians and patients; reduce adverse drug events; and serve as a tool for evaluating quality of care, cost, and patterns of drug use of older adults. Practicing clinicians, consumers, researchers, pharmacy benefits managers, regulators, and policymakers widely use the AGS Beers Criteria. According to the Beers Criteria, drug classes to avoid include benzodiazepines and benzodiazepine receptor agonists. Older adults have increased sensitivity to benzodiazepines; benzodiazepines increase risk of cognitive impairment, delirium, falls, fractures, and motor vehicle crashes. Benzodiazepine receptor agonists have adverse reactions similar to those of benzodiazepines in older adults (e.g., delirium, falls, fractures); increased emergency department visits and hospitalizations; motor vehicle crashes; minimal improvement in sleep latency and duration.[7] Therefore, a trial of a non-benzodiazepine sedative hypnotic (e.g., eszopiclone, zaleplon, zolpidem) or benzodiazepine (e.g., temazepam) will not be required for patients 65 years of age or older.

For Belsomra (suvorexant), the lowest effective dose for the patient should be used. For all Belsomra doses, take no more than once per night within 30 minutes of going to bed (with at least 7 hours remaining prior to planned awakening). The recommended dose for Belsomra is 10 mg, taken no more than once per night. If the 10 mg dose is well-tolerated but not effective, the dose can be increased. The maximum recommended dose of Belsomra is 20 mg taken no more than once per night. Belsomra is available as 5 mg, 10 mg, 15 mg, and 20 mg tablets and supplied in a package that contains 30 tablets in 3 blister cards (each blister card contains 10 tablets).[1]

The recommended dose for Dayvigo (lemborexant) is 5 mg taken no more than once per night, immediately before going to bed, with at least 7 hours remaining before the planned time of awakening. The dose may be increased to the maximum recommended dose of 10 mg based on clinical response and tolerability. Dayvigo is available as 5 mg and 10 mg tablets.[2]

REFERENCES

1. Belsomra [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.; March 2020.
2. Dayvigo [package insert]. Woodcliff Lake, NJ: Eisai; April 2020.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed February 24, 2021.
4. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed February 24, 2021.
5. 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.
6. Qaseem A, Kansagara D, Forciea 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.
7. The 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 00:1–21, 2019.

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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance? [If no, then no further questions.]	Yes	No
2	Have potential factors contributing to sleep disturbances been addressed or are currently being addressed (e.g., inappropriate sleep hygiene and sleep environment issues) as well as treatable medical/ psychiatric disorders that are co-morbid with insomnia? [If no, then no further questions.]	Yes	No
3	Is the patient 65 years of age or older? [If yes, then skip to question 7.]	Yes	No
4	Has the patient experienced an inadequate treatment response to any of the following: A) a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem), B) a benzodiazepine (e.g., temazepam)? [If yes, then skip to question 7.]	Yes	No
5	Has the patient experienced an intolerance to any of the following: A) a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem), B) a benzodiazepine (e.g., temazepam)? [If yes, then skip to question 7.]	Yes	No

6	Has the patient experienced a contraindication that would prohibit a trial of ALL of the following: A) a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem) B) a benzodiazepine (e.g., temazepam)? [If no, then no further questions.]	Yes	No
7	Does the patient require MORE than the plan allowance of 30 tablets per month? [RPh Note: If yes, then deny and enter a partial approval for 30 tablets per 25 days or 90 tablets per 75 days of Belsomra or Dayvigo]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have insomnia. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers this drug when reasons for insomnia have been addressed or are currently being addressed. Your request has been denied based on the information we have. [Short Description: No confirmation that causes of sleep disturbances have been addressed or are currently being addressed]
3.	Go to 7	Go to 4	
4.	Go to 7	Go to 5	
5.	Go to 7	Go to 6	
6.	Go to 7	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you tried another drug for insomnia (such as eszopiclone, zaleplon, zolpidem, temazepam, etc.) and it did not work for you, or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance or contraindication to a generic non-benzodiazepine sedative-hypnotic and/or a benzodiazepine]
7.	Deny	Approve, 36 months 30 tablets/25 days* or 90 tablets/75 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 30 tablets/month of the requested drug and strength. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 36 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

**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.*