

Initial Prior Authorization with Quantity Limit

Insomnia (Belsomra, Dayvigo, Quviviq)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
|------------|--------------|
| Belsomra | suvorexant |
| Dayvigo | lemborexant |
| Quviviq | daridorexant |

Indications

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

Quviviq

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

Coverage Criteria

Insomnia Characterized by Difficulties with Sleep Onset and/or Sleep Maintenance

Authorization may be granted when the requested drug is being prescribed for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance when ALL of the following criteria are met:

- 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.
- The patient meets ONE of the following:
 - The patient is 65 years of age or older.
 - The patient is less than 65 years of age and ONE of the following criteria is met:
 - The patient experienced an inadequate treatment response to ANY of the following: a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem), a benzodiazepine (e.g., temazepam).
 - The patient experienced an intolerance to ANY of the following: a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem), a benzodiazepine (e.g., temazepam).
 - The patient has a contraindication that would prohibit a trial of ALL of the following: a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem), a benzodiazepine (e.g., temazepam).

Continuation of Therapy

Insomnia Characterized by Difficulties with Sleep Onset and/or Sleep Maintenance

Authorization may be granted when the requested drug is being prescribed for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance when ALL of the following criteria are met:

- The patient has achieved or maintained a positive response to treatment from baseline.
- The patient's need for continued therapy has been assessed.
- Potential factors contributing to sleep disturbances continue to be addressed (e.g., inappropriate sleep hygiene, sleep environment issues, treatable medical/psychiatric comorbid disorders).

| Reference number(s) |
|---------------------|
| 1177-C |

Quantity Limits Apply

30 tablets per 25 days or 90 tablets per 75 days

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.

Duration of Approval (DOA)

- 1177-C: Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months

References

1. Belsomra [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; February 2023.
2. Dayvigo [package insert]. Nutley, NJ: Eisai Inc.; December 2023.
3. Quviviq [package insert]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; September 2024.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed November 27, 2024.
5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/26/2024).
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. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
8. Edinger JD, Arnedt JT, Bertisch SM, et al. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(2):255-262.
9. 2023 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2023 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults. *J Am Geriatr Soc*. 2023;71(7):2052-2081.