

Belsomra (suvorexant)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Belsomra (suvorexant), FDA approved in 2014, is a medication used to treat insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Belsomra (suvorexant) is an orexin receptor antagonist which works by blocking the action of wake-promoting proteins in the nervous system. Insomnia is a sleep disorder that can cause difficulty falling asleep or staying asleep. For chronic insomnia, both drug therapy and non-pharmacologic therapy can be used for treatment.

Definitions

"Cognitive behavioral therapy for insomnia" is a non-pharmacologic therapy focused on thoughts and behavior to improve sleep.

"Stimulus control" is a method that aims to remove the negative association between the bed and trouble sleeping.

“Relaxation training” is a method that can involve muscle relaxation, controlled breathing, and guided imagery to lower arousal states and improve sleep.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Belsomra (suvorexant)** medically necessary when **ALL** of the following criteria are met:

1. The member is 18 years of age or older; **AND**
2. The member has a diagnosis of insomnia characterized by difficulty with sleep onset and/or sleep maintenance; **AND**
3. Clinical assessment is provided showing that the member has been assessed for concurrent conditions (e.g., anxiety, chronic pain, overactive thyroid) and/or precipitating factors (e.g., certain medicines, caffeine) that are contributing to the insomnia; **AND**
4. The member has had a trial of psychological and/or behavioral therapy (such as cognitive behavioral therapy for insomnia, stimulus control, and relaxation training); **AND**
5. The member is unable to use or has adequately tried and failed a minimum **ONE** (1) month trial of at least **THREE** (3) of the following therapies:
 - a. doxepin; **and/or**
 - b. doxylamine succinate; **and/or**
 - c. eszopiclone; **and/or**
 - d. ramelteon; **and/or**
 - e. zaleplon; **and/or**
 - f. zolpidem tartrate; **AND**
6. Clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Belsomra (suvorexant) will be approved for 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if **BOTH** of the following are met:

1. the member still meets the applicable initial criteria; **AND**
2. recent chart documentation (within the last 12 months) shows the member has experienced therapeutic response to the requested medication as evidenced by **ONE** (1) of the following:

- a. clinical improvement (e.g., decreasing sleep latency) in symptoms since starting the requested medication; **or**
- b. disease stability (e.g., improving sleep maintenance) since starting the requested medication.

Experimental or Investigational / Not Medically Necessary

Belsomra (suvorexant) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Belsomra (suvorexant) [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC; February 2023.
2. Edinger, Jack D., et al. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline. *Journal of Clinical Sleep Medicine* 17.2 (2021): 255-262.
3. Qaseem A, Kansagara D, Forcica MA, Cooke M, Denberg TD; Clinical Guidelines Committee of the American College of Physicians. Management of chronic insomnia disorder in adults: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2016;165(2):125-133. doi:10.7326/M15-2175
4. Riemann D, Baglioni C, Bassetti C, et al. European guideline for the diagnosis and treatment of insomnia. *J Sleep Res*. 2017;26(6):675-700. doi:10.1111/jsr.12594
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. doi:10.5664/jcsm.6470
6. Schutte-Rodin S, Broch L, Buysse D, et al. Clinical Guideline for the Evaluation and Management of Chronic Insomnia in Adults. *J Clin Sleep Med*. 2008;4(5):487-504.
7. Winkelman JW. Overview of the treatment of insomnia in adults. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com>. Accessed July 21, 2022.

Clinical Guideline Revision / History Information

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