

## 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 (e.g., cognitive behavioral therapy for insomnia [CBT-i], stimulus control, psychoeducation/sleep hygiene interventions, sleep-restriction therapy, and relaxation training); *AND*
5. The member is unable to use or has 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 up to 12 months.

### Medical Necessity Criteria for Reauthorization

Reauthorization for up to 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

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## Clinical Guideline Revision / History Information

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