

ALASKA MEDICAID
Prior Authorization Criteria

Belsomra® (suvorexant)
Schedule IV Controlled Substance

Indication:

“Belsomra is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance”¹

Dosage Form/Strength:

Tablets: 5 mg, 10 mg, 15 mg, 20 mg

Criteria for Approval:

- The patient has a diagnosis of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance; **AND**
- The patient does not have a diagnosis of narcolepsy; **AND**,
- Other causes of sleep disturbance, such as a physical or psychiatric disorder, have been ruled out; **AND**,
- A diagnosis of sleep disturbance caused by a medication has been considered and addressed as clinically appropriate by one of the following:
 - Medication-induced sleep disturbance has been ruled out, or
 - Medications which are causing sleep disturbance have been discontinued as clinically appropriate, or
 - Medications which are causing sleep disturbance have been adjusted to minimize the effects on sleep (for example, dosing the medication earlier in the day, or decreasing the medication dosage) as clinically appropriate; **AND**,
- The patient is 18 years of age or older; **AND**
- There is documentation that the patient has tried and failed two prescription sleep aids; **AND**
- The patient has had a documented trial of cognitive behavior therapy (CBT) which must include education on sleep hygiene improvements and common misconceptions about sleep/insomnia.

Criteria for Reauthorization Approval:

- Patient meets all of the criteria for the initial authorization; **AND**,
- There is documented evidence of a positive clinical response to Belsomra therapy; **AND**,
- Evaluation for co-morbid diagnoses has been completed, and other causes of insomnia have been ruled out.

Criteria for Denial:

- The patient does not have a diagnosis of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance; **OR**

Belsomra criteria

Version 1

Last updated: 12/16/2015

Approved: 4/29/2016

Effective for Dates of Service: 10/3/2016 and thereafter

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- The patient has a diagnosis of narcolepsy; **OR**,
- Other causes of sleep disturbance, such as a physical or psychiatric disorder, have not been ruled out; **OR**,
- A diagnosis of medication- induced sleep disturbance has not been considered and addressed as clinically appropriate; **OR**,
- The patient is less than 18 years old; **OR**,
- There is no documentation that the patient has tried and failed two prescription sleep aids; **OR**,
- The patient has not had a documented trial of CBT which includes education on sleep hygiene improvements and common misconceptions about sleep/insomnia

Criteria for Reauthorization Denial:

- Patient does not meet all of the criteria for the initial authorization; **OR**,
- There is no evidence of a positive clinical response to Belsomra therapy; **OR**,
- Evaluation for co-morbid diagnoses has not been completed, and other causes of insomnia have not been ruled out.

Length of Authorization:

- Initial coverage may be approved for up to 10 days.
- Subsequent re-authorizations may be issued for up to an additional 6 months.

Quantity Limit:

- The dispensing limit is 1 tablet per day.

Mechanism of Action:

“The mechanism by which suvorexant exerts its therapeutic effect in insomnia is presumed to be through antagonism of orexin receptors. The orexin neuropeptide signaling system is a central promoter of wakefulness. Blocking the binding of wake-promoting neuropeptides orexin A and orexin B to receptors OX1R and OX2R is thought to suppress wake drive.

Antagonism of orexin receptors may also underlie potential adverse effects such as signs of narcolepsy/cataplexy. Genetic mutations in the orexin system in animals result in hereditary narcolepsy; loss of orexin neurons has been reported in humans with narcolepsy.”¹

Definitions:^{2,3}

Cognitive Behavior Therapy (CBT) is a program or a group of techniques that are used to remove factors that aggravate chronic insomnia. Some CBT techniques include stimulus control (improves the patient’s link between bed and sleep), cognitive therapy (teaches accurate expectations of sleep), sleep restriction (limit the time spent in bed to match the time spent sleeping), sleep hygiene, sleep environment improvement (such as keeping the bedroom welcoming for sleep), relaxation training (anything that reduces tension and cognitive arousal), remaining passively awake (ceasing to try so hard to fall asleep), and biofeedback (observation of biological signs which lead to insomnia).

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Sleep Hygiene is a variety of practices which promote restful, quality sleep. Some examples include: avoiding daytime naps, going to bed and rising at the same time daily, removing access to a clock, avoiding stimulants (caffeine, nicotine, pseudoephedrine, etc) close to bedtime, avoiding alcohol, avoiding large meals close to bedtime, establishing a regular relaxing bedtime routine, avoiding exercise close to bedtime, or creating a comfortable sleep environment (quiet, dark, temperature controlled).

REFERENCES / FOOTNOTES:

¹ Belsomra® Prescribing Information. Merck Sharp & Dohme Corp., Whitehouse Station, NJ. 2014. <http://www.merck.com/product/usa/pi_circulars/b/belsomra/belsomra_pi.pdf> Accessed 12/16/2015.

² Trauer JM, Qian MY, Doyle JS, Rajaratnam SM, Cunnington D. Cognitive Behavioral Therapy for Chronic Insomnia: A Systematic Review and Meta-analysis. *Ann Intern Med.* 2015;163:191-204. doi:10.7326/M14-2841.

³ Mayo Clinic Staff. "Insomnia treatment: Cognitive behavioral therapy instead of sleeping pills." February 11th, 2014. <http://www.mayoclinic.org/diseases-conditions/insomnia/in-depth/insomnia-treatment/ART-20046677> Accessed 12/16/2015.