Belsomra (suvorexant)

Background
Belsomra (suvorexant) is an orexin receptor antagonist to treat difficulty in falling and staying asleep (insomnia). Orexins are chemicals that are involved in regulating the sleep-wake cycle and play a role in keeping people awake. Belsomra alters the signaling (action) of orexin in the brain. Belsomra should be taken no more than once per night, within 30 minutes of going to bed, with at least seven hours remaining before the planned time of waking. The total dose should not exceed 20 mg once daily (1).

Regulatory Status
FDA-approved indication: Belsomra is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance (1).

Belsomra is contraindicated in patients with narcolepsy (1).

Belsomra is a central nervous system (CNS) depressant that can impair daytime wakefulness even when used as prescribed. Medications that treat insomnia can cause next-day drowsiness and impair driving and other activities that require alertness. Belsomra can impair driving skills and may increase the risk of falling asleep while driving. People can be impaired even when they feel fully awake. Patients using the 20mg strength should be cautioned against next-day driving or activities requiring full mental alertness. Patients taking lower doses should also be made aware of the potential for next-day driving impairment, because there is individual variation in sensitivity to the drug (1).
The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or mental illness that should be evaluated (1).

Warnings and precautions that should be discussed with the patient on Belsomra therapy include adverse reactions on abnormal thinking and behavioral changes (such as amnesia, anxiety, hallucinations and other neuropsychiatric symptoms), complex behaviors (such as sleep-driving, preparing and eating food, or making phone calls), dose-dependent increase in suicidal ideation, and sleep paralysis which is the inability to move or speak for up to several minutes during sleep-wake transitions (1).

No clinically meaningful differences in safety were observed between patients over 65 years of age and younger adults at recommended doses (1).

Exposure to Belsomra in obese women increased the risk of exposure-related adverse effects and should be considered before increasing the dose (1).

Safety and effectiveness in pediatric patients have not been established (1).

Related Policies
Hetlioz, Rozerem, Sedative Hypnotics

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Belsomra may be considered **medically necessary** in patients 18 years of age or older for the treatment of insomnia a persistent disorder of initiating or maintaining sleep and if the conditions indicated below are met.

Belsomra is considered **investigational** in patients less than 18 years of age and for all other indications.

### Prior-Approval Requirements

**Age** 18 years of age and older

**Diagnosis**

Patient must have the following:
1. Insomnia - a persistent disorder of initiating or maintaining sleep

AND NONE of the following:

a. Narcolepsy
b. Concurrent therapy with another sedative hypnotic agent

Prior – Approval Renewal Requirements
Same as above

Policy Guidelines

Pre - PA Allowance

Age 18 years of age and older

Quantity 30 tablets per 365 days
Duration 12 months

Prior - Approval Limits

Quantity

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 90 days</th>
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<tbody>
<tr>
<td>Belsomra 5mg</td>
<td>90 tablets per 90 days, OR</td>
</tr>
<tr>
<td>Belsomra 10mg</td>
<td>90 tablets per 90 days, OR</td>
</tr>
<tr>
<td>Belsomra 15mg</td>
<td>90 tablets per 90 days, OR</td>
</tr>
<tr>
<td>Belsomra 20mg</td>
<td>90 tablets per 90 days</td>
</tr>
</tbody>
</table>

Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Belsomra is an orexin receptor antagonist indicated for the treatment of insomnia a persistent disorder of initiating or maintaining sleep. Belsomra is contraindicated in patients with narcolepsy. Belsomra should be taken no more than once per night, within 30 minutes of going
to bed, with at least seven hours remaining before the planned time of waking. The total dose should not exceed 20 mg once daily. Belsomra therapy may cause adverse reactions on abnormal thinking and behavioral changes, complex behaviors, dose-dependent increase in suicidal ideation, and sleep paralysis which is the inability to move or speak for up to several minutes during sleep-wake transitions. Safety and effectiveness in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Belsomra while maintaining optimal therapeutic outcomes.

References