BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/17/16
LAST REVIEW DATE: 9/20/18
LAST CRITERIA REVISION DATE: 9/20/18
ARCHIVE DATE:

BELSOMRA® (suvorexant) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

BELSOMRA® (suvorexant) oral tablet (cont.)

Criteria:

- Belsomra (suvorexant) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual is 18 years of age or older

2. A confirmed diagnosis of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance

3. Individual is unable to use **ALL** of the following due to a failed response, significant adverse drug event or contraindication:
    - Benzodiazepines (at least one medication):
        - Estazolam oral tablet
        - Flurazepam HCL oral capsule
        - Temazepam oral capsule
        - Triazolam oral tablet
    - Non-benzodiazepines:
        - Eszopiclone oral tablet
        - Zaleplon oral capsule
        - Zolpidem tartrate ER oral tablet
        - Zolpidem tartrate oral tablet
    - Melatonin agonists:
        - Rozerem (ramelteon) oral tablet
    - Antidepressants:
        - Amitriptyline
        - Mirtazapine
        - Trazodone
    - Over-the-counter:
        - Diphenhydramine
        - Doxylamine

4. There are **NO** contraindications.
    - Contraindications include:
        - Individuals with narcolepsy

5. Individual does not have severe hepatic impairment (Child-Pugh Class C)

6. Individual does not have obstructive sleep apnea

7. Individual does not have severe chronic obstructive pulmonary disease

8. There is evidence of maximizing non-drug treatment(s) for insomnia

Initial approval duration: 12 months

BELSOMRA® (suvorexant) oral tablet (cont.)

- **Criteria for continuation of coverage (renewal request):** Belsomra (suvorexant) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual's condition responded while on therapy
    - Response is defined as **TWO** of the following:
        - Time to onset of sleep has improved over baseline
        - Total time asleep has improved over baseline
        - The number of night time awakenings has reduced over baseline
        - The quality of sleep has improved to feeling rested & restored on waking

2. Individual has been adherent with the medication

3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    - Contraindications as listed in the criteria for initial therapy section
    - Significant adverse effect such as:
        - Significant impairment of next morning day-time wakefulness
        - Exhibits complex sleep behaviors (such as sleep-driving) with amnesia for the events
        - Anxiety
        - Hallucinations
        - Worsening depression or suicidal thoughts
        - Sleep paralysis, hypnagogic/hypnopompic hallucinations, cataplexy-like symptoms

4. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Belsomra (suvorexant) is indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Insomnia is defined as difficulty falling asleep, difficulty staying asleep, or waking up early in the morning and not being able to return to sleep. It is associated with reduced quality of life, impaired daytime functioning, increased loss of time from work and higher heath costs. Insomnia occurs both in the presence of and in the absence of coexisting conditions and it may persist despite treatment of the coexisting condition.

There are several different categories of pharmacologic agents that can be used to treat insomnia that contain over-the-counter and prescription only drugs, included in this variety are many generic options. Categories include benzodiazepines, non-benzodiazepines, melatonin agonists, several antidepressants, and orexin antagonists. Regardless of which agent is used, behaviors that contribute to insomnia should be reviewed and modified. This includes sleep hygiene education, stimulus control, relaxation, sleep restriction, cognitive therapy, and cognitive behavioral therapy. In addition any medical or psychiatric condition that may be contributing to insomnia should be treated.

BELSOMRA® (suvorexant) oral tablet (cont.)

The Beers List or Beers Criteria is a consensus list of medications considered to be potentially harmful when used in elderly patients, defined as aged 65 years or older. The medications listed in the Beers Criteria are not meant to be viewed as definitely inappropriate in all patients. The medications should be best avoided in general and in those with certain diseases or syndromes, or prescribed at reduced dosages or used with caution or under careful monitoring.

The criteria are not meant to be applied in a punitive manner. Prescribing decisions are not always clear-cut, and clinicians must consider multiple factors, including discontinuation of other medications no longer indicated. The Beers Criteria are not meant to override clinical judgment, individual preferences, values, and needs.

Consideration of the balance between benefit to risk must be individualized for each patient to determine use of a medication that might be problematic or not. A benefit to risk assessment for each medication in a patient's overall treatment regimen should be done. The Beers Criteria should be viewed as one component of a comprehensive approach to safe use of medications in the elderly. Use of a medication on the list may be determined to be the only reasonable alternative for an individual patient.

The mechanism by which Belsomra (suvorexant) exerts its therapeutic effect in insomnia is presumed to be through antagonism of orexin receptors (OX-R). 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 OX-1R and OX-2R 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.

Resources:

Belsomra. Package Insert. Revised by manufacturer 5/2016. Accessed 9/16/16, 7/19/18.

Steinman MA, Beizer JL, DuBeau CE, et al.: How to Use the American Geriatrics Society 2015 Beers Criteria – A Guide for Patients, Clinicians, Health Systems, and Payors. J Am Geriatr Soc 2015; 63:e1–e7

American Geriatric Society 2015 Beers Criteria Update Expert Panel: American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc 2015; 63:2227–2246

UpToDate: Behavioral and pharmacologic therapies for chronic insomnia in adults. Current through Jul, 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/behavioral-and-pharmacologic-therapies-for-chronic-insomnia-in-adults?search=insomnia&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

UpToDate: Overview of the treatment of insomnia in adults. Current through Jul, 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-treatment-of-insomnia-in-adults?search=insomnia&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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Office notes, labs, and medical testing relevant to the request that show medical justification are required.