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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	January 1, 2015
Subject:	Orexin Antagonists	**Page:**	1 of 6

Last Review Date: March 12, 2021

Orexin Antagonists

Description

Belsomra (suvorexant), Dayvigo (lemborexant)

Background
Belsomra (suvorexant) and Dayvigo (lemborexant) are orexin receptor antagonists used 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 (1-2).

Regulatory Status
FDA-approved indication: Orexin receptor antagonists are indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance (1-2).

Orexin Antagonists are contraindicated in patients with narcolepsy (1-2).

Orexin Antagonists are central nervous system (CNS) depressants 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. Orexin Antagonists 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 should also be made aware of the potential for next-day driving impairment, because there is individual variation in sensitivity to the drug (1-2).

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 (1-2).

Warnings and precautions that should be discussed with the patient on Orexin Antagonist 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 (1-2).

The safety and effectiveness of Belsomra and Dayvigo in patients less than 18 years of age have not been established (1-2).

Related Policies
Hetlioz, Rozerem, Sedative Hypnotics, Xyrem

Policy

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

Orexin Antagonists 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.

Orexin Antagonists may be 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 ALL of the following:

a. Prescriber agrees to discontinue medication if patient experiences a complex sleep behavior (e.g. sleep-walking, sleep-driving, etc)
b. **NO** narcolepsy

c. **NO** concurrent therapy with another Prior Authorization (PA) sleep aid (see Appendix 1) or Xyrem (sodium oxybate)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Age 18 years of age and older

Quantity One 30 day supply per 365 days

Drug Name and Strength	Quantity Limit per 30 days
Belsomra 5mg	30
Belsomra 10mg	30
Belsomra 15mg	30
Belsomra 20mg	30
Dayvigo 5mg	30
Dayvigo 10mg	30

Prior - Approval Limits

Quantity

Drug Name	Quantity Limit per 90 days
Belsomra 5mg	90 tablets per 90 days **OR**
Belsomra 10mg	90 tablets per 90 days **OR**
Belsomra 15mg	90 tablets per 90 days **OR**
Belsomra 20mg	90 tablets per 90 days **OR**
Dayvigo 5mg	90 tablets per 90 days **OR**
Dayvigo 10mg	90 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Orexin Antagonists are indicated for the treatment of insomnia, a persistent disorder of initiating or maintaining sleep. Orexin Antagonists are contraindicated in patients with narcolepsy. Orexin Antagonist 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. The safety and effectiveness of Belsomra and Dayvigo in patients less than 18 years of age have not been established (1-2).

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

References

1. Belsomra [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; March 2020.
2. Dayvigo [package insert]. Woodcliff Lake, NJ: Eisai Inc.; April 2020.

Policy History

Date	Action
January 2015	Addition to PA
March 2015	Annual review and reference update
September 2015	Annual review
April 2016	Standardization of the definition of insomnia Policy number change from 5.07.14 to 5.60.06
June 2016	Annual review and reference update
December 2017	Annual editorial review and reference update
November 2018	Annual review and reference update
February 2019	Addition of age limit for Pre-PA
March 2019	Annual review

January 2020	Addition of Dayvigo and renamed policy Orexin Antagonists. Addition of requirement to monitor for complex sleep behaviors and revised no dual therapy requirement to include Xyrem
March 2020	Annual review and reference update
June 2020	Annual review
March 2021	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

Appendix 1 - List of PA Sleep Aids

Generic Name	Brand Name
estazolam	Prosom
eszopiclone	Lunesta
flurazepam	Dalmane
lemborexant	Dayvigo
ramelteon	Rozerem
tasimelteon	Hetlioz
suvorexant	Belsomra
temazepam	Restoril
triazolam	Halcion
zaleplon	Sonata
zolpidem	Ambien
zolpidem extended-release	Ambien CR
zolpidem oral spray	Zolpimist
zolpidem sublingual	Edluar
zolpidem sublingual	Intermezzo