

OREXIN ANTAGONISTS

BELSOMRA (suvorexant), DAYVIGO (lemborexant), QUVIVIQ* (daridorexant)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Belsomra (suvorexant), Dayvigo (lemborexant) and Quviviq (daridorexant) 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 (1-3).

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 (1-3).

Orexin Antagonists are contraindicated in patients with narcolepsy (1-3).

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 (1-3).

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 (1-3).

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), compromised respiratory function, 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 (1-3).

Orexin Antagonists should be avoided, or the dose reduced when used in combination with moderate or strong CYP3A inhibitors (1-3).

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The safety and effectiveness of Belsomra, Dayvigo, and Quviviq in patients less than 18 years of age have not been established (1-3).

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, Dayvigo, and Quviviq in patients less than 18 years of age have not been established (1-3).

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.; February 2023.
2. Dayvigo [package insert]. Woodcliff Lake, NJ: Eisai Inc.; December 2023.
3. Quviviq [package insert]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; September 2024.