

Lemborexant (DAYVIGO) Criteria for Use August 2024

VA Pharmacy Benefits Management Services and VA National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive lemborexant.

- Narcolepsy
- Co-administration with strong or moderate CYP3A4 inhibitors and inducers
- Active substance use disorder
- Actively suicidal or evaluated as being a high suicide risk
- Untreated significant sleep-related breathing disorder-obstructive or central sleep apnea syndrome
- Severe hepatic impairment (e.g., Child-Pugh C)
- History of complex sleep behaviors

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- Prescribed and monitored by a VA / VA Community Care sleep specialist or locally designated expert in sleep disorders
- Documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance
- When available, cognitive behavioral therapy for Insomnia (CBT-I) has been tried, via face to face, tele-mental health or non-VA care
- An adequate short-term trial of 2 formulary sedative hypnotics for the treatment of sleep onset and maintenance have been tried and failed to resolve symptoms or were not tolerated
- An adequate trial of daridorexant has been tried and failed or was not tolerated

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