Clinical Policy: Lemborexant (Dayvigo)

Reference Number: CP.PMN.233
Effective Date: 06.01.20
Last Review Date: 05.20
Line of Business: Commercial, HIM, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Lemborexant (Dayvigo™) is an orexin receptor antagonist.

FDA Approved Indication(s)

Dayvigo is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Dayvigo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Insomnia (must meet all)**:**

1. Diagnosis of insomnia;
2. Age ≥ 18 years;
3. Failure of two preferred or formulary agents indicated for insomnia (*see Appendix B for examples*) at maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed 10 mg (1 tablet) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Insomnia (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 10 mg (1 tablet) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
estazolam	1 mg PO HS PRN	2 mg/day
eszopiclone (Lunesta®)	1 mg – 3 mg PO HS PRN	3 mg/day
Rozerem® (ramelteon)	8 mg PO HS PRN	8 mg/day
temazepam (Restoril®)	7.5 – 30 mg PO HS PRN	30 mg/day
triazolam (Halcion®)	0.25 mg PO HS PRN	0.5 mg/day
zaleplon (Sonata®)	10 mg PO HS PRN	20 mg/day
zolpidem (Ambien® and Ambien CR®)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
Formulary status may differ based on line of business and health plan; verify formulary status prior to redirection.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): narcolepsy
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Insomnia	Recommended dose is 5 mg PO taken no more than once per night, immediately before going to bed, with at least 7	10 mg/day

Indication	Dosing Regimen	Maximum Dose
	hours remaining before the planned time of awakening. Dosage may be increased to 10 mg based on clinical response and tolerability. The maximum recommended dose is 10 mg once daily. Time to sleep onset may be delayed if taken with or soon after a meal.	

VI. Product Availability

Tablets: 5 mg, 10 mg

VII. References

1. Dayvigo Prescribing Information. Woodcliff Lake, NJ: Eisai Inc.; December 2019. Available at: https://us.eisai.com/-/media/Files/Eisai/PrescribingInformation.pdf. Accessed December 27, 2019.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 4, 2020.
3. Rosenberg R, Murphy P, Zammit G, et al. Comparison of Lemborexant With Placebo and Zolpidem Tartrate Extended Release for the Treatment of Older Adults With Insomnia Disorder. JAMA Netw Open. 2019; 2(12):e1918254. doi:10.1001/jamanetworkopen.2019.18254
4. Long-term Study of Lemborexant in Insomnia Disorder (SUNRISE 2). In ClinicalTrials.gov. NIH US National Library of Medicine. Available at: https://clinicaltrials.gov/ct2/show/NCT02952820. Accessed January 24, 2020.
5. Sateia MJ, Buysse DJ, Krystal AD, et al. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(2):307–349.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created; edited Appendix B therapeutic alternatives so that trial of zolpidem formulations (IR and CR) is equivalent to the trial of one alternative.	02.11.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.