Clinical Policy Title:	lemborexant
Policy Number:	RxA.622
Drug(s) Applied:	Dayvigo™
Original Policy Date:	05/21/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
lemborexant (Dayvigo™)	Treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance	5 mg taken no more than once per night Dosage may be increased to 10 mg based on clinical response and tolerability	10 mg daily

Dosage Forms

- Tablets: 5 mg and 10 mg

Clinical Policy

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

I. Initial Approval Criteria

A. Insomnia

1. Diagnosis of insomnia
2. Member is ≥ 18 years of age

3. (. Failure of two preferred 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. The dose does not exceed 10 mg per day.

Approval Duration:
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Insomnia

1. The member is currently receiving the medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. The member is responding positively to therapy.
3. If request is for a dose increase, new dose does not exceed 10 mg per day.

Approval Duration:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
None

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Non-Benzodiazepine Receptor Agonists		
zolpidem (Ambien®, Ambien® CR)	Varies	varies
zaleplon (Sonata®)	10 mg orally at bedtime, as needed	20 mg/day
eszopiclone (Lunesta®)	1 mg – 3 mg orally at bedtime, as needed	3 mg/day
Benzodiazepine Receptor Agonists		
temazepam (Restoril®)	7.5 – 30 mg orally at bedtime, as needed	30 mg/day
triazolam (Halcion®)	0.25 mg orally at bedtime, as needed	0.5 mg/day
flurazepam	15 to 30 mg orally at bedtime	30 mg/day
estazolam	1 mg orally at bedtime, as needed	2 mg/day
quazepam (Doral®)	7.5-15 mg at bedtime, as needed	15 mg/day
Histamine receptor antagonists		
Low-dose doxepin (Silenor®)	3-6 mg orally at bedtime, once daily	6 mg/day
Melatonin receptor agonists		

ramelteon (Rozerem®)	8 mg orally at bedtime, as needed	8 mg/day

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Dayvigo is contraindicated in patients with narcolepsy.

- Boxed Warning(s):
  - None

References

1. Dayvigo Prescribing Information. Woodcliff Lakes, NJ; Eisai Inc: April 2020. Available at www.dayvigo.com. Accessed January 19, 2021.
2. Sateia MJ, et al. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice. Journal of Clinical Sleep Medicine. 2017;13(2). doi: 10.5664/jcsm.6470, Accessed January 19, 2021.
3. Qaseem A, et al. Management of Chronic Insomnia Disorder in Adults: A Clinical Practice Guideline From the American College of Physicians. Annals of Internal Medicine. 2016;165(2):125-133. doi: 10.7326/M15-2175, Accessed January 19, 2021.
4. Insomnia drugs. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; 2020, March 17. Accessed with subscription at: http://www.micromedexsolutions.com. Accessed January, 19 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	05/07/2020	05/21/2020
Policy was reviewed: 1) Continuation therapy criteria II.A.1. added “listed in this policy” & added 3 point as “If request is for a dose increase, new dose does not exceed 10 mg per day.” 2) References were updated 3) Updated the verbiage in initial approval criteria to “Failure of two preferred…” 4) Added therapeutic alternatives table under “Appendix B”.	01/19/2021	03/09/2021