RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	**Lemborexant**
Policy Number:	RxA.622
Drug(s) Applied:	Dayvigo ®
Original Policy Date:	05/07/2020
Last Review Date:	05/07/2020
Line of Business Policy Applies to:	Commercial, Medicaid

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	5mg taken no more than once per night Dosage may be increased to 10mg based on clinical response and tolerability	10mg daily

Dosage Forms

- Tablets: 5mg and 10mg

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. The member is ≥ 18 years of age
2. The member has failed at least one drug recommended by treatment guidelines for use in patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance (i.e. temazepam (Restoril), quazepam (Doral), triazolam (Halcion), zolpidem (Ambien), zaleplon (Sonata), ramelteon (Rozerem), doxepin (Silenor), eszopiclone (Lunesta), suvorexant (Belsomra).
3. The dose does not exceed 10mg per day.

Approval Duration:
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Insomnia

1. Currently receiving 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.

Approval Duration:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
None

APPENDIX B: Therapeutic Alternatives
temazepam (Restoril), quazepam (Doral), triazolam (Halcion), zolpidem (Ambien), zaleplon (Sonata), ramelteon (Rozerem), doxepin (Silenor), eszopiclone (Lunesta), suvorexant (Belsomra)

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: December 2019. Available at www.dayvigo.com. Accessed April 13, 2020.
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
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

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	05/07/2020	05/21/2020