PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**INSOMNIA AGENTS**
BRAND NAME (generic)	
	EDLUAR (zolpidem)
	(zolpidem tartrate sublingual tablets) (generic Intermezzo)
	ZOLPIMIST (zolpidem)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Edluar
Edluar (zolpidem tartrate) sublingual tablets are indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.
The clinical trials performed with zolpidem tartrate in support of efficacy were 4-5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.

Zolpidem tartrate sublingual tablets (generic Intermezzo)
Zolpidem tartrate sublingual tablets are indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep.

Limitations of Use:
Zolpidem tartrate sublingual tablets are not indicated for the treatment of middle-of-the-night insomnia when the patient has fewer than 4 hours of bedtime remaining before the planned time of waking.

ZolpiMist
ZolpiMist (zolpidem tartrate) oral spray is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Zolpidem tartrate has been shown to decrease sleep latency for up to 35 days in controlled clinical studies. The clinical trials performed in support of efficacy were 4-5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.

COVERAGE CRITERIA

Insomnia Characterized by Difficulties with Sleep Initiation
Authorization may be granted when the requested drug is being prescribed for insomnia characterized by difficulties with sleep initiation when ALL of the following criteria are met:

- The request is for ZolpiMist (zolpidem) oral spray or Edluar (zolpidem) sublingual
- The patient is unable to swallow tablets/capsules

- Potential factors contributing to sleep disturbances have been addressed or are currently being addressed (e.g., inappropriate sleep hygiene and sleep environment issues) as well as treatable medical/psychiatric disorders that are co-morbid with insomnia

Insomnia when Middle-of-the-Night Awakening is Followed by Difficulty Returning to Sleep
Authorization may be granted when the requested drug is being prescribed for insomnia when middle-of-the-night awakening is followed by difficulty returning to sleep when ALL of the following criteria are met:

- The request is for zolpidem tartrate sublingual tablets (generic Intermezzo)
- If the patient is a biological female or a person that self-identifies as a female, then the request is for the 1.75 mg strength for a dose not exceeding 1.75 mg per day
- Potential factors contributing to sleep disturbances have been addressed or are currently being addressed (e.g., inappropriate sleep hygiene and sleep environment issues) as well as treatable medical/psychiatric disorders that are co-morbid with insomnia

CONTINUATION OF THERAPY

Insomnia Characterized by Difficulties with Sleep Initiation
Authorization may be granted when the requested drug is being prescribed for insomnia characterized by difficulties with sleep initiation when ALL of the following criteria are met:

- The request is for ZolpiMist (zolpidem) oral spray or Edluar (zolpidem) sublingual tablets
- The patient is unable to swallow tablets/capsules
- The patient has achieved or maintained a positive response to treatment from baseline
- The patient's need for continued therapy has been assessed
- Potential factors contributing to sleep disturbances continue to be addressed (e.g., inappropriate sleep hygiene, sleep environment issues, treatable medical/psychiatric comorbid disorders)

Insomnia when Middle-of-the-Night Awakening is Followed by Difficulty Returning to Sleep
Authorization may be granted when the requested drug is being prescribed for insomnia when middle-of-the-night awakening is followed by difficulty returning to sleep when ALL of the following criteria are met:

- The request is for zolpidem tartrate sublingual tablets (generic Intermezzo)
- If the patient is a biological female or a person that self-identifies as a female, then the request is for the 1.75 mg strength for a dose not exceeding 1.75 mg per day
- The patient has achieved or maintained a positive response to treatment from baseline
- The patient's need for continued therapy has been assessed
- Potential factors contributing to sleep disturbances continue to be addressed (e.g., inappropriate sleep hygiene, sleep environment issues, treatable medical/psychiatric comorbid disorders)

QUANTITY LIMITS APPLY
Edluar: 30 sublingual tablets per 25 days* or 90 sublingual tablets per 75 days*
Zolpidem tartrate sublingual tablets (generic Intermezzo): 30 sublingual tablets per 25 days* or 90 sublingual tablets per 75 days*
ZolpiMist: 4.5 mL (30 sprays/container) per 25 days* or 13.5 mL (90 sprays/3 containers) per 75 days* OR 7.7 mL (60 sprays/container) per 25 days* or 23.1 mL (180 sprays/3 containers) per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

DURATION OF APPROVAL (DOA)

- 387-C: Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months

REFERENCES

1. Edluar [package insert]. Somerset, NJ: Meda Pharmaceuticals Inc.; August 2022.
2. Zolpidem tartrate sublingual [package insert]. Chestnut Ridge, NY: Par Pharmaceutical; October 2019.

3. ZolpiMist [package insert]. Englewood, CO: Aytu BioScience, Inc.; August 2019.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed November 28, 2023.
5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/28/2023).
6. 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.
7. American Academy of Sleep Medicine. International Classification of Sleep Disorders, 3rd edition, text revision. American Academy of Sleep Medicine, 2023.
8. Edinger JD, Arnedt JT, Bertisch SM, et al. Behavioral and psychological treatment for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(2):255-262.