PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**INSOMNIA AGENTS**
BRAND NAME (generic)	
	EDLUAR (zolpidem)
	INTERMEZZO (zolpidem)
	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.

Intermezzo
Intermezzo (zolpidem tartrate) sublingual tablet is 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: Intermezzo is 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 assessment of sleep latency performed at the end of treatment.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- Potential causes of sleep disturbances have been addressed or are currently being addressed (e.g., inappropriate sleep hygiene and sleep environment issues or treatable medical/psychological disorders that are co-morbid with insomnia)

AND

- The request is for ZolpiMist (zolpidem) oral spray or Edluar (zolpidem) sublingual tablets **AND**
  - The requested drug is being prescribed for insomnia characterized by difficulties with sleep initiation **AND**
  - The patient is unable to swallow tablets/capsules

  OR
- The request is for Intermezzo (zolpidem) sublingual tablets **AND**

- The requested drug is being prescribed for insomnia when middle-of-the-night awakening is followed by difficulty returning to sleep
  AND
- If the patient is a biological female or a person that self-identifies as a female, the request is for the 1.75 mg strength for a dose not exceeding 1.75 mg per day

Quantity Limits apply.
30 tablets/month

REFERENCES

1. Edluar [package insert]. Somerset, NJ: Meda Pharmaceuticals Inc.; August 2019.
2. Intermezzo [package insert]. Stamford, CT: Purdue Pharma L.P.; August 2019.
3. ZolpiMist [package insert]. Englewood, CO: Aytu BioScience, Inc.; August 2019.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed February 24, 2021.
5. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed February 24, 2021.
6. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. 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. Qaseem A, Kansagara D, Forciea MA, Cooke M, Denberg TD, Management of chronic insomnia disorder in adults: A clinical practice guideline from the American College of Physicians. *Ann Intern Med*. Epub, 2016. 165(2):125-33. doi: 10.7326/M15-2175. Epub 2016 May 3.
8. Schutte-Rodin S, Broch L, Buysse D, Dorsey C, Sateia M. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med 2008;* 4(5):487-504.