PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS</th>
<th>INSOMNIA AGENTS</th>
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<tbody>
<tr>
<td>BRAND NAME</td>
<td>(generic)</td>
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<td></td>
<td>EDLUAR SUBLINGUAL TABLETS</td>
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<td></td>
<td>(zolpidem)</td>
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<td>INTERMEZZO SUBLINGUAL TABLETS</td>
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<td></td>
<td>(zolpidem)</td>
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<td>ZOLPIMIST ORAL SPRAY</td>
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<td>(zolpidem)</td>
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Status: CVS Caremark Criteria  
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Edluar
Edluar sublingual tablets are indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. The clinical trials performed with Edluar 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 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 oral spray is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. ZolpiMist 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

ZolpiMist (zolpidem) oral spray and Edluar (zolpidem) sublingual tablets
The requested drug will be covered with prior authorization when the following criteria are met:

- The drug is being prescribed for insomnia characterized by difficulties with sleep initiation
  AND
- Potential causes of sleep disturbances have been addressed (e.g., inappropriate sleep hygiene and sleep environment issues or treatable medical/psychological causes of chronic insomnia)
The requested drug will be covered with prior authorization when the following criteria are met:

- The drug is being prescribed for insomnia when middle-of-the-night awakening is followed by difficulty returning to sleep
- Potential causes of sleep disturbances have been addressed (e.g., inappropriate sleep hygiene and sleep environment issues or treatable medical/psychological causes of chronic insomnia)
- The patient is one of the following: biological male or a person that self-identifies as a male, 65 years of age and under, or not taking the requested drug concomitantly with other CNS depressants (e.g., benzodiazepines, opioids, tricyclic antidepressants, alcohol)
- The patient is one of the following: biological female or a person that self-identifies as a female, over 65 years old or taking the requested drug concomitantly with other CNS depressants (e.g., benzodiazepines, opioids, tricyclic antidepressants, alcohol)
  - The request is for the 1.75 mg strength for a dose not exceeding 1.75 mg per day

Quantity Limits apply.

REFERENCES