Hypnotic Sedatives
Step Therapy Policy
May 2017

OVERVIEW
Eszopiclone, zaleplon, zolpidem immediate-release (IR), zolpidem extended-release (ER), zolpidem sublingual tablets, Edluar, and Zolpimist are all non-benzodiazepine sedative hypnotics used for the treatment of insomnia. These agents interact with gamma-aminobutyric acid (GABA) receptor complexes located closely to benzodiazepine receptors; the chemical structures of these agents are unrelated to the benzodiazepines. All seven are schedule IV controlled substances. Rozerem, another non-benzodiazepine sedative hypnotic, is a melatonin receptor agonist. Silenor is a tricyclic compound that acts as a histamine H₁ receptor antagonist. Neither Rozerem nor Silenor are controlled substances. Belsomra is a first-in-class orexin receptor antagonist and is a schedule IV controlled substance.

Doxepin is also available generically as oral capsules (10, 25, 50, 75, 100, and 150 mg) and oral solution (10 mg/mL). These higher dose formulations are recommended for use in patients with depression and/or anxiety of varying etiologies. In 2008, prior to the availability of Silenor, a clinical guideline for the evaluation and management of insomnia in adults was published. The guideline indicates that short-term hypnotic treatment should be supplemented with behavioral and cognitive therapies when possible. Over-the-counter (OTC) antihistamine or antihistamine/analgesic type drugs (OTC “sleep aids”) as well as herbal and nutritional substances (e.g., melatonin) are not recommended in the treatment of chronic insomnia due to the relative lack of efficacy and safety data. In addition, several agents used for insomnia are on the 2012 Beers list of medications that are categorized as potentially inappropriate agents for elderly persons aged ≥ 65 years (e.g., amitriptyline, benzodiazepines, chloral hydrate, doxepin [> 6 mg/day]); zolpidem, zaleplon, and eszopiclone should not be used chronically (> 90 days).

DRUGS AFFECTED:
- Ambien® (zolpidem tablets)
- Ambien CR® (zolpidem extended-release tablets)
- Belsomra® (suvorexant tablets)
- Edluar® (zolpidem 5 and 10 mg sublingual tablets)
- Intermezzo® (zolpidem 1.75 and 3.5 mg sublingual tablets)
- Lunesta® (eszopiclone tablets)
- Rozerem® (ramelteon tablets)
- Silenor® (doxepin 3 and 6 mg tablets)
- Sonata® (zaleplon capsules)
- Zolpimist® (zolpidem oral spray)

POLICY STATEMENT
A step therapy program has been developed to encourage the use of one generic Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. The following step therapy criteria are for those of 18 years of age and over. All approvals are provided for 1 year in duration.
Step 1: generic eszopiclone tablets, generic zaleplon capsules, generic zolpidem immediate-release tablets, generic zolpidem extended-release tablets, generic zolpidem sublingual tablets

Step 2: Ambien, Ambien CR, Belsomra, Edluar, Intermezzo, Lunesta, Rozerem, Silenor, Sonata, Zolpimist

Criteria

1. If the patient has tried a Step 1 agent, then approve a Step 2 agent.

2. Exceptions can be made for Rozerem or Silenor if the patient has a documented history of addiction to controlled substances.

3. An exception for Rozerem can be made in patients ≥ 65 years of age.

4. Exceptions can be made for Edluar or Zolpimist if the patient has difficulty swallowing or cannot swallow tablets.

5. No other exceptions are recommended.

References

• Sonata® capsules [prescribing information]. Bristol, TN: King Pharmaceuticals; November 2016.
• Rozerem® tablets [prescribing information]. Lincolnshire, IL: Takeda Pharmaceuticals, Inc; November 2010.
• Silenor® tablets for oral administration [prescribing information]. San Diego, CA: Somaxon Pharmaceuticals, Inc; March 2010.
• Belsomra® tablets [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2016.