MEDICAL MUTUAL®

Drug Policy

Policy: **Impacted Drugs:**	**Sedative Hypnotics** **Step Therapy Policy** **Ambien (zolpidem)** **Ambien CR (zolpidem extended-release)** **Belsomra (suvorexant)** **Dayvigo (lemborexant)** **Edluar (zolpidem 5 and 10 mg sublingual tablets)** **Generic Doxepin (3mg and 6mg capsules)** **Intermezzo (zolpidem 1.75 and 3.5 mg sublingual tablets)** **Lunesta (eszopiclone)** **Quviviq (daridorexant)** **Rozerem (ramelteon)** **Silenor (doxepin 3 and 6 mg)** **Sonata (zaleplon)** **Generic Zolpidem capsules** **Zolpimist (zolpidem oral spray)**	**Annual Review Date: 03/21/2024** **Last Revised Date: 03/21/2024**

OVERVIEW

Eszopiclone, zaleplon, zolpidem immediate-release (IR), zolpidem extended-release (ER), zolpidem sublingual tablets, Edluar, Quviviq and Zolpimist are all non-benzodiazepine sedative hypnotics used for the treatment of insomnia. These products interact with gamma-aminobutyric acid (GABA) receptor complexes located closely to benzodiazepine receptors; the chemical structures of these products 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 H_1 receptor antagonist. Neither Rozerem nor Silenor are controlled substances. Belsomra and Dayvigo are orexin receptor antagonists and are both schedule IV-controlled substances.

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 products used for insomnia are on the 2012 Beers list of medications that are categorized as potentially inappropriate products 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).

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POLICY STATEMENT

A step therapy program has been developed to encourage the use of one generic Preferred product prior to the use of a non-preferred product. If the step therapy rule is not met for a non-preferred product 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.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy. For Silenor and generic doxepin 3 mg and 6 mg tablets, a patient who is ≥ 65 years of age will not be targeted by this Step Therapy program.

Preferred products:

- Generic eszopiclone tablets
- Generic ramelteon tablets
- Generic zaleplon capsules
- Generic zolpidem immediate-release tablets
- Generic zolpidem extended-release tablets

Non-preferred products:

- Belsomra
- Dayvigo
- Edluar
- Generic doxepin 3 mg and 6 mg tablets
- Generic Zolpidem Capsules
- Generic zolpidem sublingual tablets
- Quviviq
- Silenor
- Sonata
- Zolpimist

CRITERIA

1. If the patient has tried a preferred product, then approve a non-preferred product.

2. Exceptions can be made for Silenor or generic doxepin 3mg or 6mg tablets if the patient has a documented history of addiction to controlled substances.

3. An exception for generic doxepin 3 mg or 6 mg tablets or Silenor 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.

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Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred products. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred products. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred products. If so, please list the contraindications to each preferred product [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred product after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred product for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred product for 90 days AND that the patient has been receiving the requested non-preferred product via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred product) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other products, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

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