MEDICAL MUTUAL®

Drug Policy

Policy:	Sedative Hypnotics Step Therapy Policy	Annual Review Date: 03/20/2025
Impacted Drugs:	• Belsomra (suvorexant) • Dayvigo (lemborexant) • Intermezzo (zolpidem 1.75 and 3.5 mg sublingual tablets) • Quviviq (daridorexant) • doxepin 3 and 6 mg – generic to Silenor • Sonata (zaleplon) • zolpidem capsules – generic • Edluar (zolpidem 5 and 10 mg sublingual tablets) – generics, Meda • Zolpimist (zolpidem oral spray)	Last Revised Date: 03/20/2025

OVERVIEW

The products included in this policy are indicated for the treatment of insomnia.

- Zolpidem immediate-release (IR), Edluar, Zolpimist, and zaleplon, non-benzodiazepine sedative hypnotics, are indicated for the **short-term treatment of insomnia**.[1,3,5,6]
- Eszopiclone, a non-benzodiazepine; Silenor, a tricyclic compound; and Rozerem, a melatonin receptor agonist, are also indicated for the treatment of **insomnia**, but their product labeling does not specifically limit their use to short-term.[2,4,8,9]
- Zaleplon and Rozerem are specifically indicated for the treatment of insomnia characterized by difficulty with sleep onset.[3,8]
- Zolpidem IR, zolpidem extended-release (ER), Silenor, and eszopiclone have also been shown to improve sleep maintenance or increase the duration of sleep.[1,2,4,9]
- Belsomra, Dayvigo, and Quviviq, orexin receptor antagonists, are indicated for the **treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance**.[10-12]
- Zolpidem 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**.[7] However, zolpidem sublingual tablets are not indicated for treatment of middle-of-the-night insomnia when the patient has fewer than 4 hours of bedtime remaining before the planned time of waking.
- Zolpidem Capsules is a branded product indicated for **short-term treatment of transient insomnia** in adults < 65 years of age.[17]

Eszopiclone, zaleplon, zolpidem, Belsomra, Dayvigo, and Quviviq are schedule IV controlled substances.[1-7,10-12,17] Neither Rozerem nor Silenor are controlled substances.[8,9]

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.

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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 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
- Sonata
- Zolpimist

CRITERIA

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

2. Exceptions can be made for 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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Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 years (730 days)
B) *Extended Approval:* 2 years (730 days)

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*; **OR**
B. The patient has a contraindication to all preferred products. If so, please list the contraindications to each preferred product*; **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 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.

References

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