

Pharmacy Policy Bulletin

Title: Sleep Agents

Policy #: FS.CLIN.37

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This pharmacy policy will be reviewed regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent

Zolpidem tartrate extended-release (Ambien CR®) is a nonbenzodiazepine hypnotic that is indicated in the treatment of individuals who have insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

Ramelteon (Rozerem®) is a melatonin receptor agonist that is indicated in the treatment of insomnia characterized by difficulty with sleep onset.

Zolpidem tartrate (Edluar®) and (Zolpimist) are nonbenzodiazepine hypnotics indicated for the treatment of insomnia characterized by difficulties with sleep initiation.

Doxepin (Silenor) is indicated for the treatment of insomnia characterized by difficulties with sleep maintenance.

The use of zolpidem tartrate extended-release (Ambien CR®), ramelteon (Rozerem®), doxepin (Silenor), zolpidem (Zolpimist) and zolpidem tartrate sublingual tablets (Edluar®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Description:

Zolpidem tartrate extended-release (Ambien CR®), zolpidem (Zolpimist) and zolpidem sublingual tablets (Edluar®) exert a hypnotic effect by binding to the alpha-1 subunit of GABA receptors. Zolpidem tartrate extended-release (Ambien CR®) is not structurally related to any current hypnotic medication. It is a bi-layered tablet, with one layer releasing its drug content immediately, and the other layer releasing its content at a slower rate. Currently, zolpidem tartrate extended-release (Ambien CR®) is classified as a Schedule III controlled substance.

Ramelteon (Rozerem®) is a selective human melatonin MT1 receptor agonist. It has no affinity to benzodiazepine, dopamine, or opiate receptors. Unlike melatonin, it does not exhibit activity at the serotonin 5-HT1a or the dopamine D1 receptor. Interaction with the MT1 receptor occurs in the hypothalamic suprachiasmatic nucleus, the area of the brain believed to mediate the circadian effects of melatonin.

Doxepin (Silenor) is a tricyclic antidepressant with potent H1 histamine blocking activity. The sleep maintenance effect is believed to be caused by its H1 antagonist effect.

Policy

Zolpidem tartrate extended-release (Brand Ambien CR®) is approved when **all** of the following inclusion criteria are met:

- Documentation of a diagnosis of insomnia
- Documentation of a trial and failure of zolpidem tartrate immediate-release-containing product and Eszopiclone (Lunesta®)

Ramelteon (Rozerem®) is approved when **all** of the following inclusion criteria are met:

- Documentation of a diagnosis of insomnia
- Documentation of **one** of the following:
 - Documentation of a trial and failure of zolpidem tartrate immediate-release-containing product and Eszopiclone (Lunesta®)
 - Documentation of abuse potential

Zolpidem tartrate sublingual tablet (Edluar®) is approved when **all** of the following inclusion criteria are met:

- Documentation of a diagnosis of insomnia
- Documentation of **one** of the following:
 - Documentation of a trial and failure of zolpidem tartrate immediate-release-containing product and Eszopiclone (Lunesta®)
 - Documentation of the inability to swallow capsules/tablets (eg, dysphagia, gastrointestinal [GI] tubes)

Doxepin (Silenor) is approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of insomnia
- Documentation of a trial and failure/contraindication/intolerance of zolpidem tartrate immediate-release-containing product and Eszopiclone (Lunesta)

Zolpidem (Zolpimist) oral spray is approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of insomnia

Documentation of a trial and failure/contraindication/intolerance of zolpidem tartrate immediate-release-containing tablets and Eszopiclone (Lunesta®)

Guidelines

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any products that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References

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Applicable Drugs

i Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Drug Name	Strength and/or formulation
Zolpidem tartrate extended-release (Ambien CR)	All
Ramelteon (Rozerem)	All

Zolpidem sublingual tablets (Edluar)	All
Doxepin (Silenor)	All
Zolpidem (Zolpimist)	All

✚ Cross References

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