Policies Repository

Independence Blue Cross

Policy Title	Sleep Agents
Policy Number	FS.CLIN.20

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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.

Policy

Zolpidem tartrate extended-release (Ambien CR®) and **eszopiclone (Lunesta®)** are nonbenzodiazepine hypnotics that are 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®) is a nonbenzodiazepine hypnotic indicated for the treatment of insomnia characterized by difficulties with sleep initiation. Its safety and efficacy has not been established in children. Currently, zolpidem tartrate sublingual (Edluar®) is classified as a Schedule IV controlled substance.

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

Policy Description

Zolpidem tartrate extended-release (Ambien CR®) 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.

Eszopiclone (Lunesta®) interacts with GABA receptors at binding domains that are located near or attached to GABA receptors, but the specific mechanism of action is not known. Eszopiclone (Lunesta®) is not structurally related to any current hypnotic medication. Currently, eszopiclone (Lunesta®) 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.Currently, ramelteon (Rozerem®) is classified as a Schedule III controlled substance.

Policy Guideline Inclusion

Eszopiclone (Lunesta®) and **zolpidem tartrate extended-release (Ambien CR®)** are approved when **all** of the following inclusion criteria are met:

- Diagnosis of insomnia
- Documentation of a trial and failure of a zolpidem tartrate immediate-release-containing product for a minimum of 14 days

Ramelteon (Rozerem®) is approved when the following inclusion criterion is met:

- Diagnosis of insomnia

In addition, **one** of the following criteria must also be met in order for **ramelteon (Rozerem®)** to be approved:

- Documentation of a trial and failure of a zolpidem tartrate immediate-release-containing product for a minimum of 14 days
- Documentation of abuse potential

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

- Diagnosis of insomnia
- Documentation of **one** of the following:
    - Trial and failure of a zolpidem tartrate immediate-release-containing product for a minimum of 14 days
    - Documentation of the inability to swallow capsules/tablets (eg, dysphagia, gastrointestinal [GI] tubes)

Policy Guideline Exclusion

Eszopiclone (Lunesta®), zolpidem tartrate extended-release (Ambien CR®), and **ramelteon (Rozerem®)** are denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of insomnia
- No documentation of a trial and failure of a zolpidem tartrate immediate-release-containing product for a minimum of 14 days

Zolpidem tartrate sublingual (Edluar®) is denied when **any** of the following inclusion criteria are present:

- No diagnosis of insomnia
- No documentation of **one** of the following:
    - Trial and failure of a zolpidem tartrate immediate-release-containing product for a minimum of 14 days
    - Documentation of the inability to swallow capsules/tablets (eg,

dysphagia, gastrointestinal [GI] tubes)

Policy List of Applicable Drugs

Brand Name	Generic Name
Ambien CR	zolpidem tartrate extended-release
Lunesta	eszopiclone
Rozerem	ramelteon
Edluar	zolpidem sublingual tablets

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

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Policy Link to Related Policies

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