

Policies Repository



Policy Title Sleep Agents

Policy Number FS.CLIN.20

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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.

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

Policy Description

Zolpidem tartrate extended-release (Ambien CR®) exerts 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

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

Policy List of Applicable Drugs

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

Refer to the specific manufacturer's prescribing information for administration and

Dosing and Administration

dosage details for each specific agent.

Policy References

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Policy Link to Related Policies

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