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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	December 7, 2011
Subject:	Sedative Hypnotics	**Page:**	1 of 8

Last Review Date: March 12, 2021

Sedative Hypnotics

Description

Ambien (zolpidem), Ambien CR (zolpidem extended-release), Dalmane (flurazepam), Edluar (zolpidem sublingual), Halcion (triazolam), Intermezzo (zolpidem sublingual) Lunesta (eszopiclone), Prosom (estazolam), Restoril (temazepam), Sonata (zaleplon), Zolpimist (zolpidem) Oral Spray

Background
Insomnia is defined as complaints of disturbed sleep in the presence of adequate opportunity and circumstance for sleep. The disturbance can consist of one or more of three features: difficulty in initiating sleep; difficulty in maintaining sleep; or waking up too early. Insomnia can be primary or secondary to a variety of medical illnesses, psychiatric disorders, or drug use. Identifying and treating potential underlying conditions or comorbid diagnoses are priorities in the treatment of insomnia. In order to treat insomnia, various treatment modalities should be considered, such as sleep hygiene, sleep restriction, stimulus control and cognitive behavioral therapy, prior to the addition of pharmacotherapy, and continued throughout pharmacotherapy treatment (1-2).

The treatment of insomnia should be individualized and is dependent on the differential diagnosis. Although short-term therapy is appropriate for most patients, some patients may benefit from long-term use. Patients with insomnia that occurs several days per week and lasts for more than a month may have the diagnosis of chronic insomnia. There are indications that long-term management of chronic insomnia may be beneficial. Long-term management of chronic insomnia is achievable when pharmacotherapy is considered for use only in response to

the occurrence of the symptoms, thus permitting long-term therapy without the use of nightly medication (1).

Regulatory Status
FDA-approved indication: Sedative hypnotics are indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation (2-13).

Use of sedative-hypnotics can cause serious side-effects including cognitive impairment, rebound insomnia, morning sedation, falls and dependence (2).

Non-pharmacologic interventions have been shown to produce consistent and sustained improvements for insomnia. These approaches include sleep hygiene, stimulus control, sleep restriction, paradoxical intention, and relaxation therapy (2).

Some of the sedative hypnotics have a boxed warning regarding complex sleep behaviors, including sleep-walking, sleep-driving, and engaging in other activities while not fully awake. Discontinue sedative hypnotics immediately if a patient experiences a complex sleep behavior (3-13).

Related policies
Hetlioz, Orexin Antagonists, Rozerem, Xyrem

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Ambien (zolpidem), Ambien CR (zolpidem extended-release), Edluar (zolpidem sublingual), Dalmane (flurazepam), Halcion (triazolam), Intermezzo (zolpidem sublingual), Lunesta (eszopiclone), Prosom (estazolam), Restoril (temazepam), Sonata (zaleplon), Zolpimist (zolpidem oral spray) may be considered **medically necessary** in patients that are 18 years and older with a confirmed diagnosis of insomnia and if the conditions indicated below are met.

Ambien (zolpidem), Ambien CR (zolpidem extended-release), Edluar (zolpidem sublingual), Dalmane (flurazepam), Halcion (triazolam), Intermezzo (zolpidem sublingual), Lunesta (eszopiclone), Prosom (estazolam), Restoril (temazepam), Sonata (zaleplon), Zolpimist (zolpidem oral spray) may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Insomnia – a persistent disorder of initiating or maintaining sleep

AND ALL of the following:

1. Prescriber agrees to discontinue sedative hypnotic if patient experiences a complex sleep behavior (e.g. sleep-walking, sleep-driving, etc)
2. **NO** concurrent therapy with another Prior Authorization (PA) sleep aid (see Appendix 1) or Xyrem (sodium oxybate)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Age 18 years of age and older

Quantity One 30 day supply per 365 days

Drug Name	Strength	Quantity Limit per 30 days
Ambien/Zolpidem	5mg	60
Ambien/Zolpidem	10mg	30
Ambien CR/Zolpidem ER	6.25mg	60
Ambien CR/Zolpidem ER	12.5mg	30
Dalmane/Flurazepam	15mg	60
Dalmane/Flurazepam	30mg	30
Edluar/Zolpidem SL	5mg	60
Edluar/Zolpidem SL	10mg	30
Halcion/Triazolam	0.125mg	120

Halcion/Triazolam	0.25mg	60
Intermezzo/Zolpidem SL	1.75mg	60
Intermezzo/Zolpidem SL	3.5mg	30
Lunesta/Eszopiclone	1mg	90
Lunesta/Eszopiclone	2mg	30
Lunesta/Eszopiclone	3mg	30
Prosom/Estazolam	1mg	60
Prosom/Estazolam	2mg	30
Restoril/Temazepam	7.5mg	120
Restoril/Temazepam	15mg	60
Restoril/Temazepam	22.5mg	30
Restoril/Temazepam	30mg	30
Sonata/Zaleplon	5mg	120
Sonata/Zaleplon	10mg	60
Zolpimist oral spray	5mg/spray	1 canister

Prior - Approval Limits

Quantity

Drug Name	Strength	Quantity Limit per 90 days
Ambien/Zolpidem	5mg	180
Ambien/Zolpidem	10mg	90
Ambien CR/Zolpidem ER	6.25mg	180
Ambien CR/Zolpidem ER	12.5mg	90
Dalmane/Flurazepam	15mg	180
Dalmane/Flurazepam	30mg	90
Edluar/Zolpidem SL	5mg	180
Edluar/Zolpidem SL	10mg	90

Halcion/Triazolam	0.125mg	360
Halcion/Triazolam	0.25mg	180
Intermezzo/Zolpidem SL	1.75mg	180
Intermezzo/Zolpidem SL	3.5mg	90
Lunesta/Eszopiclone	1mg	270
Lunesta/Eszopiclone	2mg	90
Lunesta/Eszopiclone	3mg	90
Prosom/Estazolam	1mg	180
Prosom/Estazolam	2mg	90
Restoril/Temazepam	7.5mg	360
Restoril/Temazepam	15mg	180
Restoril/Temazepam	22.5mg	90
Restoril/Temazepam	30mg	90
Sonata/Zaleplon	5mg	360
Sonata/Zaleplon	10mg	180
Zolpimist oral spray	5mg/spray	3 canisters

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Insomnia is defined as complaints of disturbed sleep in the presence of adequate opportunity and circumstance for sleep. The disturbance can consist of one or more of three features: difficulty in initiating sleep; difficulty in maintaining sleep; or waking up too early (1).

The treatment of insomnia should be individualized and is dependent on the differential diagnosis. Although short-term therapy is appropriate for most patients, some patients may benefit from long-term use. Patients with insomnia that occurs several days per week and lasts

for more than a month may have the diagnosis of chronic insomnia. Use of sedative-hypnotics can cause serious side-effects including cognitive impairment, rebound insomnia, morning sedation, falls and dependence (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of sedative-hypnotics while maintaining optimal therapeutic outcomes.

References

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11. Restoril [package insert]. Hazelwood, MO: Mallinckrodt Inc; September 2017.
12. Sonata [package insert]. New York, NY: Pfizer Inc.; May 2013.
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Policy History

Date	Action
January 2005	Revised to include the new strength of Restoril (temazepam) 22.5mg
July 2009	Addition of Edluar 5mg and 10mg sublingual tablets containing active ingredient zolpidem, FDA approved for the treatment of insomnia.
December 2010	Addition of Zolpimist 5mg oral spray, FDA approved for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Each Zolpimist actuation delivers 5mg of zolpidem and is available in a 7.7ml single stock canister that delivers 60 sprays.
April 2012	Addition of Intermezzo 1.75mg and 3.5mg sublingual tablets containing active ingredient zolpidem, FDA approved for the treatment of insomnia.

December 2012	Increased Sonata maximum daily dose limit to 20mg per package insert. Although the risk of certain adverse events associated with the use of Sonata appears to be dose dependent, the 20 mg dose has been shown to be adequately tolerated and may be considered for the occasional patient who does not benefit from a trial of a lower dose (11). Annual editorial review and update.
September 2014	Annual editorial review and reference update Addition of age requirement 18 years or older to align with the FDA guidelines.
March 2015	Annual editorial review and reference update Addition of no concurrent therapy with another sedative hypnotic agent
September 2016	Annual editorial review and reference update Addition of no concurrent use with Xyrem (sodium oxybate)
December 2017	Annual editorial review and reference update
November 2018	Annual editorial review and reference update Addition of age limit for Pre-PA
November 2019	Addition of boxed warning to regulatory status and requirement to discontinue sedative hypnotic if patient experiences a complex sleep behavior
December 2019	Annual review
May 2020	Revised no dual therapy requirement
June 2020	Annual review
March 2021	Annual editorial review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

Appendix 1 - List of PA Sleep Aids

Generic Name	Brand Name
estazolam	Prosom
eszopiclone	Lunesta
flurazepam	Dalmane
lemborexant	Dayvigo
ramelteon	Rozerem
tasimelteon	Hetlioz
suvorexant	Belsomra
temazepam	Restoril
triazolam	Halcion
zaleplon	Sonata
zolpidem	Ambien
zolpidem extended-release	Ambien CR
zolpidem oral spray	Zolpimist
zolpidem sublingual	Edluar
zolpidem sublingual	Intermezzo