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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	December 7, 2011
Subject:	Sedative Hypnotics	**Page:**	1 of 9

Last Review Date: December 8, 2023

Sedative Hypnotics

Description

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

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication

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 (2-15).

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 (3-15).

Related policies
Hetlioz, Orexin Antagonists, Rozerem, Xyrem, Xywav

Policy

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

Sedative Hypnotics may be considered **medically necessary** if the conditions indicated below are met.

Sedative Hypnotics may be considered **investigational** 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 with an oxybate product (see Appendix 2)

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	5 mg	60
Ambien/Zolpidem	10 mg	30
Ambien CR/Zolpidem ER	6.25 mg	60
Ambien CR/Zolpidem ER	12.5 mg	30
Dalmane/Flurazepam	15 mg	60
Dalmane/Flurazepam	30 mg	30
Quazepam	15 mg	30
Edluar/Zolpidem SL	5 mg	60
Edluar/Zolpidem SL	10 mg	30
Halcion/Triazolam	0.125 mg	120
Halcion/Triazolam	0.25 mg	60
Intermezzo/Zolpidem SL	1.75 mg	60

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

Prior - Approval Limits

Quantity

Drug Name	Strength	Quantity Limit per 90 days
Ambien/Zolpidem	5 mg	180
Ambien/Zolpidem	10 mg	90
Ambien CR/Zolpidem ER	6.25 mg	180
Ambien CR/Zolpidem ER	12.5 mg	90
Dalmane/Flurazepam	15 mg	180
Dalmane/Flurazepam	30 mg	90
Quazepam	15 mg	90
Edluar/Zolpidem SL	5 mg	180
Edluar/Zolpidem SL	10 mg	90
Halcion/Triazolam	0.125 mg	360

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

Drug name with Approved Formulary Exception Only	**Strength**	**Quantity Limit for 90 days**
Doral brand	15 mg	90
Zolpidem capsule	7.5 mg	90

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. Lunesta [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; August 2019.
12. Restoril [package insert]. Hazelwood, MO: Mallinckrodt Inc; January 2023.
13. Sonata [package insert]. New York, NY: Pfizer Inc.; August 2019.
14. Zolpimist [package insert]. Louisville, KY: Magna Pharmaceuticals, Inc.; August 2019.
15. Zolpidem tartrate capsule [package insert]. Morristown, NJ: Almatica Pharma LLC; May 2023

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
May 2021	Revised no dual therapy requirement
June 2021	Annual review and reference update. Addition of Doral to policy per FEP
December 2021	Annual review. Doral (brand name only) requires formulary exception + PA
September 2022	Annual editorial review. Added Quviviq to Appendix 1
June 2023	Added zolpidem capsule 7.5mg to policy as a product requiring formulary exception + PA
September 2023	Annual review

December 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.

Appendix 1 - List of Prior Authorization (PA) Sleep Aids

Generic Name	Brand Name
daridorexant	Quviviq
estazolam	Prosom
eszopiclone	Lunesta
flurazepam	Dalmane
lemborexant	Dayvigo
quazepam	Doral
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

Appendix 2 - List of Oxybate Products

Generic Name	Brand Name
sodium oxybate	Xyrem
calcium, magnesium, potassium, sodium oxybates	Xywav