Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Sedative Hypnotics Step Therapy**

Effective: February 10, 2026

Guideline Type	☐ Prior Authorization ☐ Non-Formulary ☒ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

This guideline applies to the following medications:

- **Belsomra (suvorexant)**
- **Edluar (zolpidem tartrate)**

AND

- **Silenor (doxepin hydrochloride tablets)**

Since sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit following a reasonable period of treatment may indicate the presence of a primary psychiatric and/or medical illness that requires evaluation. Worsening of insomnia, or the emergence of new cognitive or behavioral abnormalities, may be the result of an unrecognized underlying psychiatric or physical disorder requiring further evaluation.

Ambien (zolpidem tartrate conventional tablets) is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

Ambien CR (zolpidem extended-release) is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance (as measured by wake time after sleep onset).

Belsomra (suvorexant) is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Edluar (zolpidem tartrate) sublingual tablet is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

Intermezzo (zolpidem) sublingual tablets are indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep.

Lunesta (eszopiclone) is indicated for the treatment of insomnia. In controlled outpatient and sleep laboratory studies, Lunesta (eszopiclone) administered at bedtime decreased sleep latency and improved sleep maintenance

Rozerem (ramelteon) is indicated for the treatment of insomnia characterized by difficulty with sleep onset. The clinical trials preformed in support of efficacy were up to six months in duration.

Sonata (zaleplon) is indicated for the short-term treatment of insomnia.

Silenor (doxepin hydrochloride tablets) are indicated for the treatment of insomnia characterized by difficulty with sleep maintenance.

****doxepin capsules could be used off-label for treatment of insomnia and are covered on all of our commercial and Direct formularies for patients 13 years of age and older. PA applies for patients age 12 and under.****

Clinical Guideline Coverage Criteria

Note: Prescriptions that meet the initial step therapy requirements will adjudicate **automatically** at the point of service. If the patient does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan for patients who do not meet the step therapy criteria at the point of service.

Please refer to the table below for mediations subject to this policy:

Drug	Premium	Value/Select	Core
Step-1			
eszopiclone	Covered	Covered	Covered
zaleplon			
zolpidem tartrate			
ramelteon			
Step-2			
Belsomra (suvorexant)	Requires prior use of a drug on Step-1 or Step-2	Requires prior use of a drug on Step-1 or Step-2	Requires prior use of a drug on Step-1 or Step-2
Edluar (zolpidem)		Non-formulary	Non-formulary

Automated Step Therapy Coverage Criteria

The following stepped approach applies to coverage of the Step-2 medications by the plan:

Step 1: Medications on Step-1 are covered without prior authorization

Step 2: The plan may cover Step-2 medications if the following criteria are met:

a. The patient has had a trial of a Step-1 or Step-2 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan

Coverage Criteria for Patients not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

The following stepped approach applies to sedative hypnotic treatments covered by the plan:

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

a. The patient has had previous trial of a Step-1 or Step-2 medication as evidenced by physician documented use

OR

b. The patient has a physician documented contraindication or intolerance to all Step-1 medication

Note: The plan may cover medications on Step-2 if a patient has received a non-formulary medication, containing the same therapeutic ingredient as a lower step agent, as evidenced by physician documented use.

<u>Silenor (doxepin hydrochloride tablets):</u>

Please refer to the table below for medications subject to this policy:

Drug	
Step-1	
doxepin capsules*	Covered
eszopiclone	
zaleplon	
zolpidem tartrate	
ramelteon	
Step-2	
doxepin tablets (generic Silenor)	Requires prior use of a drug on Step-1 or Step-2

*PA required for age 12 and younger

Automated Step Therapy Coverage Criteria

The following stepped approach applies to coverage of the Step-2 medications by the plan:

Step 1: Medications on Step-1 are covered without prior authorization

Step 2: The plan may cover Step-2 medications if the following criteria are met:

b. The patient has had a trial of a Step-1 or Step-2 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan

Coverage Criteria for Patients not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

The following stepped approach applies to doxepin tablets:

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

c. The patient has had previous trial of a Step-1 or Step-2 medication as evidenced by physician documented use

OR

d. The patient has a physician documented contraindication or intolerance to all Step-1 medication

Note: The plan may cover medications on Step-2 if a patient has received a non-formulary medication, containing the same therapeutic ingredient as a lower step agent, as evidenced by physician documented use

Limitations

- Medications on Step-2 are not covered unless the above step therapy criteria are met.
- Step therapy point of service coding does not apply to any non-formulary medications. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

Codes

None

References:

1. Ambien (zolpidem) [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; February 2025.
2. Ambien CR (zolpidem extended-release) [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; February 2025.
3. Belsomra (suvorexant) [package insert]. Whitehouse Station, NJ: Merck & Co.; March 2025.
4. Edluar (zolpidem) [package insert]. Somerset, NJ: Meda Pharmaceuticals Inc; August 2022.
5. Elie R, Rüther E, Farr I, et al for the Zaleplon Study Group. Sleep latency is shortened during 4 weeks of treatment with zaleplon, a novel nonbenzodiazepine hypnotic. *J Clin Psychiatry*. 1999; 60:536-44.
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8. Hurst M, Noble S. Zaleplon. *CNS Drugs*. 1999;11:387-92.
9. Intermezzo [package insert]. Stamford, CT: Purdue Pharma L.P.; July 2015.
10. Kryger MH, Steljes D, Pouliot Z, et al. Subjective versus objective evaluation of hypnotic efficacy: experience with zolpidem. *Sleep*. 1991;14:399-407.
11. Krystal AD, Walsh JK, Laska E, et al. Sustained efficacy of eszopiclone over 6 months of nightly treatment: results of a randomized, double-blind, placebo-controlled study in adults with chronic insomnia. *Sleep*. 2003;26:793-9.
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13. Lunesta (eszopiclone) [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; January 2025.
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15. Rozerem (ramelteon) [package insert]. Lexington, MA: Takeda Pharmaceuticals America Inc.; July 2025.
16. Silenor (doxepin) [package insert]. Morristown, NJ: Currax Pharmaceuticals LLC.; May 2023.
17. Sonata (zaleplon) [package insert]. Bristol, TN: King Pharmaceuticals Inc.; March 2023.
18. Wagner J, Wagner ML, Hening WA. Beyond benzodiazepines: alternative pharmacologic agents for the treatment of insomnia. *Ann Pharmacotherapy*. 1998;32:680-91.
19. Walsh JK, Fry J, Erwin CW, et al. Efficacy and tolerability of 14-day administration of zaleplon 5mg and 10mg for the treatment of primary insomnia. *Clin Drug Invest*. 1998;16:347-54.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- May 9, 2023: Effective June 1, 2023, consolidated Silenor ST MNG with Sedative Hypnotic MNG. No additional criteria changes.
- February 13, 2024: Effective May 1, 2024, removed criterion pertaining to patient or prescribing provider's office is located in Rhode Island.
- February 11, 2025: No changes
- February 10, 2026: Removed Zolpimist (zolpidem) from the Medical Necessity Guideline because the product has been discontinued. Updated table within Medical Necessity Guideline to capture addition of Select formulary for 2026.
- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.