NC Division of Medical Assistance **Medicaid**
Outpatient Pharmacy **Effective Date: May 1, 2006**
Prior Approval Criteria **Amended Date: March 1, 2024**
Sedative Hypnotics

Therapeutic Class Code: H2E, H8B
Therapeutic Class Description: Sedative Hypnotics—Non-Barbiturate, Hypnotics, Melatonin MT1/MT2 Receptor Agonists

Medication
Ambien, Ambien CR, zolpidem, zolpidem ER, Zolpimist, zolpidem SL,Edluar
zaleplon
estazolam
flurazepam
Halcion, triazolam
Doral
Restoril, temazepam
Lunesta, eszopiclone
Rozerem, ramelteon
Silenor, doxepin
Belsomra
Dayvigo
Quviviq

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.

b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to
correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements
If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.

IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
EPSDT provider page: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Criteria

Exceeding Quantity Limit of 15 units per Calendar Month (oral tablets/capsules/SL tablets) or Zolpimist (oral spray) –one canister per 60days

a. Beneficiary must have a diagnosis of chronic primary insomnia lasting one month or longer. Beneficiary must have received information on good sleep hygiene and have a documented trial (at least 3 weeks) of non-pharmacological therapies (e.g. stimulus control, sleep restriction, sleep hygiene measures and relaxation therapy). Length of therapy may be approved for up to six months at a time.
OR
b. Beneficiary must have a diagnosis of chronic secondary or co-morbid insomnia lasting one month or longer and has been evaluated for and is being actively treated for one of the following conditions:
   1. an underlying psychiatric illness associated with insomnia
   2. an underlying medical illness associated with insomnia (for example, chronic pain associated with cancer, inflammatory arthritis)
   3. a sleep disorder such as restless legs syndrome, sleep-related breathing disorder, sleep-related movement disorder, or circadian rhythm disorder. Length of therapy may be approved for up to six months at a time.

   OR
c. Beneficiary is being discontinued from a sedative hypnotic and tapering is required to prevent

symptoms of withdrawal. Length of therapy may be approved for up to three months at a time.
OR

d. Beneficiary is being actively assessed for a diagnosis of chronic primary or secondary/co-morbid insomnia. Beneficiary must have received information on good sleep hygiene and have a documented trial (at least 3 weeks) of non-pharmacological therapies (e.g. stimulus control, sleep restriction, sleep hygiene measures and relaxation therapy). Length of therapy may be approved for six months one time only. Additional information may be requested to substantiate this status.

Procedures

a. Changes in strength will not require additional prior authorization.
b. Prior authorization request forms will be accepted when submitted by mail or facsimile telecommunication methods only.
c. Beneficiaries residing in skilled nursing facilities, intermediate care facilities, and intermediate care facilities for individuals with mental retardation are exempt from the prior authorization requirement for sedative hypnotics.

FDA Recommendations 2013

To reduce risk of next-morning impairment after use of insomnia drugs; FDA requires lower recommended doses for certain drugs containing zolpidem and warns about risks of next day impairment (Ambien, Ambien CR, Edluar, and Zolpimist)"

a. **For certain immediate-release zolpidem products (Ambien, Edluar, and Zolpimist) the recommended initial dose for women should be lowered from 10 mg to 5 mg, immediately before** bedtime. Lower dose of 5 mg for men should be considered as well. For both men and women, the 5 mg dose could be increased to 10 mg if needed, but the higher dose is more likely to impair next-morning driving and other activities that require full alertness.

b. **For extended-release zolpidem (Ambien CR) the recommended initial dose for women should be lowered from 12.5 mg to 6.25 mg, immediately before bedtime. Lower dose of 6.25 mg in men should be considered in men as well**. For both men and women, the 6.25 mg dose can be increased to 12.5 mg if needed, but the higher dose is more likely to impair next-morning driving and other activities that require full alertness.

c. For zolpidem and other insomnia drugs, prescribe the lowest dose that treats the patient's symptoms.

d. **The FDA urges health care professionals to caution all patients (men and women) who use these products about the risks of next-morning impairment for activities that require complete mental alertness, including driving**. Inform patients that impairment from sleep drugs can be present despite feeling fully awake.

e. **Patients who take the sleep medication zolpidem extended-release (Ambien CR)—either 6.25 mg or 12.5 mg—should not drive or engage in other activities that require complete mental alertness the day after taking the drug** because zolpidem levels can remain high enough the next day to impair these activities. This new recommendation has been added to the *Warnings and Precautions* section of the physician label and to the patient Medication Guide for zolpidem extended-release (Ambien CR).

Glossary[18]

a. **Chronic Insomnia:** Insomnia may be defined as complaints of disturbed sleep in the presence of adequate opportunity and circumstance for sleep. The disturbance may consist of one or more of three features: (1) difficulty in initiating sleep; (2) difficulty in maintaining sleep; or (3) waking up too early. A fourth characteristic, non-restorative or poor-quality sleep, has frequently been included in the definition, although there is controversy as to whether individuals with this complaint share similar pathophysiologic mechanisms with the others. Chronic insomnia has been defined by the recent NIH consensus panel as 30 days or more of the symptoms described above.

b. **Primary Chronic Insomnia:** "Primary insomnia" is the term used when no coexisting disorder has been identified.

c. **Secondary or Co-Morbid Insomnia**: Most cases of insomnia are co-morbid with other conditions. Historically, this has been termed "secondary insomnia." However, the limited understanding of mechanistic pathways in chronic insomnia precludes drawing firm conclusions about the nature of these associations or the direction of causality.

References

1. Sanofi-Synthelabo Inc. Ambien package insert. New York: March 2004.
2. Sanofi-Synthelabo Inc. Ambien CR package insert. New York: Sept. 2005.
3. ICN Pharmaceuticals, Inc. Dalmane package insert. Costa Mesa, CA: Sept. 2001.
4. Medpointe Healthcare, Inc. Doral package insert. Somerset, NJ: 2001.
5. Pharmacia Corp. Halcion package insert. Kalamazoo, MI: Jan. 2003.
6. Abbott Laboratories. ProSom package insert. Chicago, Il, Jan. 2004.
7. Mallinckrodt, Inc. Restoril package insert. St. Louis, MO.
8. Wyeth Pharmaceuticals. Sonata package insert. Philadelphia, PA: Dec. 2004.
9. *Insomnia: Assessment and Management in Primary Care.* NIH Publication No. 98-4088. Sept. 1998.
10. *Manifestations and Management of Chronic Insomnia in Adults*. NIH State-of-the-Science Conference Statement. June 15, 2005.
11. *Drug Class Review on Newer Sedative-Hypnotics, Final Report.* Portland, OR: Oregon Evidence-based Practice Center, Oregon Health and Science University, Dec. 2005.
12. Buscemi N, Vandermeer B, Friesen C, Bialy L, Tubman M, Ospina M, Klassen TP, Witmans M. Manifestations and Management of Chronic Insomnia in Adults. Evidence Report/Technology
13. Assessment No. 125. (Prepared by the University of Alberta Evidence-based Practice Center, under Contract No. C400000021.) AHRQ Publication No. 05-E021-2. Rockville, MD: Agency for Healthcare Research and Quality. June 2005.
14. American Academy of Family Physicians. Information from your family doctor: Sleep changes in older adults. *Am Fam Physician* 2005 Oct 1;72(7):1315-6.
15. American Academy of Family Physicians. Information from your family doctor. Insomnia: how to get a good night's sleep. *Am Fam Physician*. 2005 Oct 1;72(7):1309-10.
16. Patient handout. Sleep talk with your doctor. *Geriatrics*. 2004 Jan;59(1):33-4.
17. Parmet S, Lynm C, Glass RM. JAMA patient page. Insomnia. *JAMA*. 2003 May 21;289(19):2602.
18. Page for patients. Sleep. Prev Med. *Prev Med.* 2002 Jun;34(6):579-80.
19. National Institutes of Health State of the Science Conference statement on Manifestations and Management of Chronic Insomnia in Adults, June 13-15, 2005. Sleep. 2005 Sep 1;28(9):1049-57.

20. ECR Pharmaceuticals. Zolpimist package insert. Richmond, Virginia: 2010
21. Belsomra Package Insert. Merck, Sharp, and Dome., 2014.
22. Quviviq Package Insert. Idorsia Pharmaceuticals; Radnor, PA: April, 2022.

Criteria Change Log

05/01/2006	Criteria effective date
05/15/2009	Coverage for up to 15 units per drug class without PA
12/13/2011	Add coverage for Zolpimist and dosing limits
09/13/2012	Added FDA guidance for zolpidem dosing
08/01/2014	Update quantity limits
08/15/2014	Removed brand name Prosom and Dalmane
06/10/2015	Add coverage for Belsomra
07/09/2020	Remove GSNs, add generic ramelteon, generic eszopiclone, generic zolpidem SL, Remove brand name Sonata
04/13/2021	Add generic for Doxepin
04/13/2021	Add Dayvigo
03/01/2024	Add Quviviq, Remove brand name Intermezzo, remove NC Health Choice