

**NC Division of Medical Assistance
Outpatient Pharmacy
Prior Approval Criteria
Antinarcoticeps/Antihyperkinesis Agents**

**Medicaid and Health Choice
Effective Date: March 4, 2002
Amended Date: March 15, 2021**

Therapeutic Class Code: H8Q, H1G

Therapeutic Class Description: Antinarcoticeps/Antihyperkinesis Agents

Medication
Provigil, modafinil
Nuvigil, armodafinil
Sunosi
Wakix
Xyrem
Xywav

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.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries.**

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **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 beneficiary 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 practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or 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:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

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Service limitations on scope, amount, duration, frequency, location of service, and 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.

b. EPSDT and Prior Approval Requirements

1. 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.
2. **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>

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age:

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within the **Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

**A. Criteria for modafinil (Provigil) and armodafinil (Nuvigil)
Initial Approval Criteria**

Approval will be considered as treatment to improve wakefulness for beneficiaries who:

- Have a diagnosis of narcolepsy. **OR**
- Have excessive sleepiness associated with shift work sleep disorder. **OR**
- Require adjunct treatment for a diagnosis of obstructive sleep apnea/hypopnea syndrome (OSAHS) with concurrent use of continuous positive airway pressure (CPAP) if CPAP is the treatment of choice **OR**
- Have excessive fatigue associated with multiple sclerosis or myotonic dystrophy

Procedure

- Approval length one year.
- The maximum daily dose for modafinil is 400 mg.
- The maximum daily dose for armodafinil is 250 mg.

Renewal Criteria

- Beneficiary must continue to meet the above initial criteria; **AND**
- Beneficiary reports documented reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale)

B. Criteria for Sunosi

Initial Approval Criteria

Approval will be considered as treatment to improve wakefulness for beneficiaries who:

- Are ≥ 18 years old; **AND**
- Have a diagnosis of obstructive sleep apnea (OSA) OR narcolepsy; **AND**
- Do not have end stage renal disease (estimated glomerular filtration rate [eGFR] < 15 mL/min/1.73 m²); **AND**
- Have blood pressure assessed and hypertension controlled ($\leq 140/90$ mmHg) prior to initiating treatment; **AND**
- Are not receiving a monoamine oxidase inhibitor (MAOI) and have not received a MAO inhibitor within 14 days; **AND**
- Are not receiving concomitant noradrenergic medications; **AND**
- Have tried and failed an adequate trial of at least one preferred drug in the Anti-Narcolepsy class on the NC Medicaid Preferred Drug List (PDL); **AND**
- If used for OSA, beneficiary must meet the following requirements:
 - Prescriber attestation that beneficiary is compliant with and will continue using positive airway pressure (PAP); **AND**
 - Prescriber has excluded any other identifiable causes for patient's sleepiness (e.g., non-compliance with PAP, improperly fitted PAP mask, insufficient sleep, poor sleep hygiene, depression, and/or other sleep disorders);

Renewal Criteria

- Beneficiary must continue to meet the above initial criteria; **AND**

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- Beneficiary has not developed increased blood pressure or heart rate that was not controlled by a dose reduction of solriamfetol or medical intervention. **AND**
- Beneficiary reports documented reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale)

Procedure

- Initial approval duration: 3 months
- Renewal approval duration: 6 months

C. Criteria for Wakix

Initial Approval Criteria

- Beneficiary is ≥ 18 years old; **AND**
- Beneficiary has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for ≥ 3 months; **AND**
- Beneficiary must not be receiving treatment with sedative hypnotic agents (e.g., zolpidem, eszopiclone, zaleplon, benzodiazepines, barbiturates); **AND**
- Beneficiary will not use drugs that prolong the QT interval (e.g., quinidine, procainamide, disopyramide, amiodarone, sotalol, ziprasidone, chlorpromazine, thioridazine, moxifloxacin) concomitantly; **AND**
- Beneficiary will not use histamine-1 (H1) receptor antagonists (e.g., pheniramine maleate, diphenhydramine, promethazine, imipramine, clomipramine, mirtazapine) concomitantly; **AND**
- Beneficiary does not have a history of prolonged QTc interval (e.g., QTc interval > 450 milliseconds); **AND**
- Beneficiary does NOT have end-stage renal disease (estimated glomerular filtration rate [eGFR] < 15 mL/min/1.73 m²); **AND**
- Beneficiary does NOT have severe hepatic impairment; **AND**
- Beneficiary has a diagnosis of cataplexy with narcolepsy; **OR**
- Beneficiary has a diagnosis of narcolepsy; **AND**

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- Beneficiary must have had an adequate documented trial and failure of, or contraindication to, modafinil and armodafinil

Renewal Criteria

- Beneficiary must continue to meet the above initial criteria; **AND**
- For diagnosis of narcolepsy: Beneficiary reports documented reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale); **AND**
- For diagnosis of cataplexy with narcolepsy: reduced frequency of cataplexy attacks from pretreatment baseline
- Beneficiary has NOT experienced any treatment-restricting adverse effects(e.g., abnormal behavior, abnormal dreams or nightmares, anhedonia, anxiety, bipolar disorder, depression or depressed mood, nausea, QT prolongation, sleep disorder, suicide attempt or suicidal ideation).

D. Criteria for Xyrem & Xywaz

Initial Approval Criteria

- Beneficiary is ≥ 7 years of age; **AND**
- Beneficiary has no current use of alcohol, or sedative hypnotics; **AND**
- Beneficiary does not have succinic semialdehyde dehydrogenase deficiency; **AND**
- Beneficiary has been evaluated for history of drug abuse; **AND**
- Prescriber will monitor for signs of misuse or abuse of sodium oxybate (a.k.a. gamma-hydroxybutyrate [GHB]) including, but not limited to, the following:
 - Use of increasingly large doses, increased frequency of use, drug seeking behavior, feigned cataplexy, etc.; **AND**
- Diagnosis of cataplexy associated with narcolepsy; **OR**
- Diagnosis of excessive daytime sleepiness due to narcolepsy with daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for ≥ 3 months; **AND**
 - Hypersomnolence secondary to another sleep disorder, neurologic disorder, medical condition, or by medicine or substance use has been ruled out

Renewal Criteria

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- Beneficiary must continue to meet the above initial criteria; **AND**
- For Excessive Daytime Sleepiness: Response to therapy with a reduction in excessive daytime sleepiness from pre-treatment baseline as measured by a validated scale (e.g., Epworth Sleepiness Scale, Stanford Sleepiness Scale, Karolinska Sleepiness Scale, Cleveland Adolescent Sleepiness Questionnaire, or a Visual Analog Scale); **AND**
- For Cataplexy - reduced frequency of cataplexy attacks from pretreatment baseline

References

1. Prescriber Information—PROVIGIL® (pro-vij-el) Tablets [C-IV]—Generic name: modafinil. Cephalon, Inc. West Chester, PA 19380. February 2004.
2. Ballon JS, Feifel D. A systematic review of modafinil: potential clinical uses and mechanisms of action. *Journal of Clinical Psychiatry*. 2006 April; 67(4):554-566.
3. Fava M, Thase ME, DeBattista C. A multicenter, placebo controlled study of Modafinil augmentation in partial responders to selective serotonin reuptake inhibitors with persistent fatigue and sleepiness. *Journal of Clinical Psychiatry*. 2005 January; 66(1):85-93.
4. Prescriber Information—NUVIGIL ® (armodafinil) Tablets (C-IV). Cephalon, Inc. Frazer, PA 19355. July 2008.
5. Lange Rudiger, et al. Modafinil effects in multiple sclerosis patients with fatigue. *Journal of Neurology*. 2009 April; 256: 645-650.
6. Rammohan, K, et al. Efficacy and Safety of modafinil (Provigil®) for the treatment of fatigue in multiple sclerosis: a two centre phase 2 study. *Journal of Neurology, Neurosurgery, and Psychiatry*. 2002;72:179-183.
7. Prescriber Information- SUNOSI®. Palo Alto, CA; Jazz; March 2019.
8. Wakix [package insert]. Plymouth Meeting, PA; Harmony Biosciences; August 2019. Updated October 2020
9. Xywav [package insert]. Palo Alto, CA; Jazz; July 2020.
10. Xyrem [package insert]. Palo Alto, CA; Jazz; July 2020.

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Criteria Change Log	
03/04/2002	Criteria effective date
07/10/2007	Added requirement for CPAP and diagnosis of Obstructive Sleep Apnea/Hypopnea Syndrome
08/10/2009	Added coverage for Nuvigil
09/14/2011	Added coverage for diagnoses of Multiple Sclerosis and Myotonic Dystrophy
06/15/2012	Added modafinil and Nuvigil
09/13/2012	Added GCN 36082 for Nuvigil
05/22/2018	Added armodafinil
10/13/2020	Removed GCN's Added Sunosi Updated EPSDT information Added criteria for Wakix
03/15/2021	Added criteria for Xyrem & Xywaz Added cataplexy with narcolepsy as approvable diagnosis for Wakix