This information was supplied by the NC Medicaid Division of Health Benefits.

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

Medicaid and Health Choice
Effective Date: March 4, 2002
Amended Date: May 22, 2018

Therapeutic Class Code: H8Q
Therapeutic Class Description: Antinarcolepsy/Antihyperkinesis Agents

Medication	Generic Code Number(s)	NDC Number(s)
Provigil, modafinil	26101, 26102	
Nuvigil, armodafinil	98590, 98591, 98592, 36082	

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 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.

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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

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IFPRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents
coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria

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

- Have a diagnosis of narcolepsy.
- Have excessive sleepiness associated with shift work sleep disorder.
- 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
- 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.

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. Modafanil 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.

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