Generic Name: Armodafinil

Therapeutic Class or Brand Name: Nuvigil®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 6140001000

Preferred: Armodafinil tablets (generic)

Non-preferred: Nuvigil® tablets

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 10/5/2018

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:

   A. Excessive sleepiness associated with narcolepsy and criterion 1 is met:

      1. History of treatment failure, intolerance, or contraindication to at least one formulary alternative (i.e. methylphenidate, dextroamphetamine).

   B. Excessive sleepiness associated with treated obstructive sleep apnea and criterion 1 is met:

      1. Documentation that the patient has been compliant with CPAP or BiPAP for at least 2 months.

   C. Excessive sleepiness associated with shift work sleep disorder and criteria 1 through 4 are met:

      1. Documentation that the patient is working night shifts.
      2. Documentation that sleep disturbance causes specific measurable functional impairment in social, occupational, or other important areas of functioning that has persisted for at least 3 months.
      3. Documentation that sleep disturbance is not due to otherwise reversible conditions (i.e. another sleep disorder, mental disorder, or physiologic effect of another substance).
      4. Documentation that non-pharmacologic therapies (i.e. planned sleep schedules, timed light exposure) have been inadequate in improving functional impairments.

II. Minimum age requirement: 17 years old.

III. Documented failure (after a minimum of a 6 week trial), intolerance, or contraindication to modafinil.

IV. Non-preferred products (i.e. Nuvigil® tablets) require a documented clinical reason containing details as to why generic armodafinil is not appropriate or is contraindicated.

EXCLUSION CRITERIA

- Nuvigil® (armodafinil) and Provigil® (modafinil) are mutually exclusive. Patients may only have a prior authorization for one of these medications at a time.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities of up to 30 tablets per 30 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing the medication is effective.

APPENDIX

N/A

REFERENCES

1. https://www.policy.regence.com/trgmedpol/drugs/dru185.pdf .
2. https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Nuvigil.pdf.
3. www.drugs.com .
4. https://npsonline.pti-nps.com .
5. http://nuvigil.com/PDF/Full_Prescribing_Information.pdf .

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
10/5/2018	1. **Replaced** reference #1 http://blue.regence.com/trgmedpol/drugs/dru185.pdf (obsolete) with https://www.policy.regence.com/trgmedpol/drugs/dru185.pdf . 2. **Replaced** reference #2 https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Nuvigil.pdf (obsolete) with https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Nuvigil%20(armodafinil)-Provigil%20(modafinil).pdf .

12/1/2017	1. Policy reviewed: no changes made.
9/28/2016	1. **Changed** "N/A" **to** "Preferred: Armodafinil tablets (generic); Non-Preferred: Nuvigil® tablets" **following Applicable Drugs**. 2. **Added** "IV. Non-preferred products (i.e. Nuvigil® tablets) require a documented clinical reason containing details as to why generic armodafinil is not appropriate or is contraindicated" **under Prior Authorization Criteria**. 3. **Changed** "Nuvigil® (armodafinil), Provigil® (modafinil), and generic modafinil are mutually exclusive..." **to** "Nuvigil® (armodafinil) and Provigil® (modafinil) are mutually exclusive..." **under Exclusion Criteria**.
11/4/2015	1. **Added** "Documented failure (after a minimum of a 6 week trial), intolerance, or contraindication to modafinil" **under Prior Authorization Criteria**.
3/10/2015	1. **Changed** "Nuvigil® (armodafinil) and Provigil® (modafinil) are mutually exclusive. Patients may only have a prior authorization for one of these medications at a time" **to** "Nuvigil® (armodafinil), Provigil® (modafinil), and generic modafinil are mutually exclusive. Patients may only have a prior authorization for one of these medications at a time" **under Exclusion Criteria**. 2. **Updated** "Quantities of up to 30 tablets per month" **to** "Quantities of up to 30 tablets per 30 days" **under Quantity/Days Supply Restrictions**. 3. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/allentries.php" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Nuvigil.pdf" **under References**.
10/16/2013	1. **Adapted policy to new format**. 2. **Removed** "Failure on a ≥ 6 week trial of, or contraindication to, Modafinil (Provigil®)" **requirement**. 3. **Added** "Excessive sleepiness associated with" **in front of each covered diagnosis**. 4. **Changed criteria for narcolepsy from:** "Amphetamines or Methylphenidate must be tried first" **to** "History of treatment failure, intolerance, or contraindication to at least one formulary alternative (i.e. methylphenidate, dextroamphetamine)". 5. **Changed criteria for treated obstructive sleep apnea from:** "Must be on CPAP" **to** "Documentation that the patient has been compliant with CPAP or BiPAP for at least 2 months". 6. **Changed criteria for shift work sleep disorder from:** "Must be working night shifts; Provide documentation of a treatment plan that demonstrates excessive sleepiness at work and insomnia when the patient should be sleeping; A three month trial of sleep aids must be tried first" **to** "Documentation that the patient is working night shifts; Documentation that sleep

	disturbance causes specific measurable functional impairment in social, occupational, or other important areas of functioning that has persisted for at least 3 months; Documentation that sleep disturbance is not due to otherwise reversible conditions (i.e. another sleep disorder, mental disorder, or physiologic effect of another substance; Documentation that non-pharmacologic therapies (i.e. planned sleep schedules, timed light exposure) have been inadequate in improving functional impairments". 7. **Removed dose limit information** from under specific diagnoses, **and replaced with quantity restriction** of 30 tablets per month under "Quantity/Days Supply Restrictions" section. 8. **Updated references** to include specific Regence policy referred to and Nuvigil Prescribing Information.