MEDICATION POLICY

Generic Name: Modafinil

Therapeutic Class or Brand Name: Provigil®

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Modafinil tablets (generic)

Non-Preferred: Provigil® tablets

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 9/28/16

GPI Code: 6140002400

Prior Authorization Criteria (may be considered medically necessary when criteria I and III 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, tmed light exposure) have been inadequate in improving functional impairments.

II. Minimum age requirement: 17 years old.

III. Non-preferred products (i.e. Provigil® tablets) require a documented clinical reason containing details as to why generic modafinil 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. http://blue.regence.com/trgmedpol/drugs/dru058.pdf.
2. https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Provigil.pdf.
3. www.drugs.com.
4. https://npsonline.pti-nps.com.
5. http://www.provigil.com/PDFs/prescribing_info.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
9/28/2016	1. **Changed** "Modafinil (generic Provigil®)" **to** "Preferred: Modafinil tablets (generic); Non-Preferred: Provigil® tablets" **following Applicable Drugs (if Therapeutic Class)**. 2. **Added** "III. Non-preferred products (i.e. Provigil® tablets) require a documented clinical reason containing details as to why generic modafinil 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**. 4. **Updated** "http://www.provigil.com/media/PDFs/prescribing_info.pdf" **to** "http://www.provigil.com/PDFs/prescribing_info.pdf" **under References**.
11/4/2015	1. **Removed** "Documented failure (after a minimum of a 6 week trial), intolerance, or contraindication to Nuvigil® (armodafinil)" **from Prior Authorization Criteria**.
3/10/2015	1. **Changed** "N/A" to "Modafinil (generic Provigil®)" **under Applicable Drugs**. 2. **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**. 3. **Updated** "Quantities of up to 30 tablets per month" **to** "Quantities of up to 30 tablets per 30 days" **under Quantity/Days Supply Restrictions**. 4. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/allentries.php" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Provigil.pdf" **under References**.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
10/16/2013	1. **Adapted policy to new format.** 2. **Changed minimum age requirement** from 9 years old to 17 years old because "safety and effectiveness in pediatric patients, below age 17, have not been established". 3. **Added** "Documented failure (after a minimum of a 6 week trial), intolerance, or contraindication to Nuvigil® (armodafinil)" **requirement**. 4. **Removed "**Treatment to offset sedation related to Multiple Sclerosis treatment modalities" as a covered diagnosis because new data show modafinil is not effective in improving fatigue associated with multiple sclerosis. 5. **Added** "Excessive sleepiness associated with" **in front of each covered diagnosis**. 6. **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)". 7. **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". 8. **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". 9. **Removed dose limit information** from under specific diagnoses, **and replaced with quantity restriction** of 30 tablets per month under "Quantity/Days Supply Restrictions" section. 10. **Updated references** to include specific Regence policy referred to and Provigil Prescribing Information.