ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Provigil® (modafinil)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Provigil® (modafinil)

Diagnosis (documentation supportive of diagnosis is required)

☐ Narcolepsy (polysomnogram and MSLT required)

Excessive Daytime Fatigue related to:
☐ Shift Worker's Sleep Disorder (documentation of shift work, excessive sleepiness at the time of the night shifts, and documented daytime insomnia required)

☐ Obstructive Sleep Apnea (polysomnogram and documentation of Positive Airway Pressure therapy [CPAP, BPAP, APAP] or oral appliance use required)
☐ Trial of PAP therapy not tolerated (documentation of reasoning is required)

☐ Other (clinical notes related to diagnosis required): _____

Physician Specialty

Original diagnosis must be made by Neurologist or Sleep disorder specialist
Primary care provider may make subsequent requests

☐ Sleep Disorder Specialist
☐ Neurologist
☐ PCP-Family Practice
☐ Other: _____

Name of Sleep Disorder Specialist or Neurologist who made original diagnosis: _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐ Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Provigil (modafinil)

CLASSIFICATION

- CNS Stimulant (amphetamine related)

DESCRIPTION

- Modafinil is a central nervous system stimulant. Structurally, modafinil is a benzhydrylsulfinylacetamide compound and bears only a distant similarity to dextroamphetamine. The precise mechanism of action of modafinil in producing stimulatory effects is unclear. It appears to lack the peripheral sympathomimetic effects observed with amphetamines.
- Modafinil has been shown to reduce excessive daytime sleepiness (EDS) in patients with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder.

Narcolepsy:

- Modafinil was shown to be safe and effective for the treatment of narcolepsy in a large, double-blind, randomized trial conducted by the US Modafinil in Narcolepsy Multicenter Study Group. Patients with EDS were allocated to modafinil 200 mg (n=93) or 400 mg/day (n=81) or placebo (n=87) for the 9-week study period. After 9 weeks, mean scores on the subjective Epworth Sleepiness Scale were significantly lower for both modafinil groups vs. placebo ($p < 0.001$). Patients receiving modafinil did significantly better on 2 objective measures of sleepiness, the Multiple Sleep Latency Test ($p < 0.001$) and the Maintenance of Wakefulness Test ($p < 0.001$). No significant differences occurred between the 2 modafinil groups. Adverse effects were most commonly headache and nausea, were mostly rated mild to moderate, and appeared to be dose-dependent.
- In a dose-comparison study in 75 narcolepsy patients, modafinil 400 mg daily was not significantly more effective than 200 mg daily, but the higher dose was associated with a higher frequency of nausea and nervousness.
- Comparisons of modafinil with agents that have proven effective in narcolepsy, including methylphenidate, pemoline, and dextroamphetamine, are needed to clarify its relative safety and efficacy, and place in therapy.

Obstructive sleep apnea as an adjunct to standard treatment(s) to improve excessive sleepiness, for the underlying obstruction:

- In a randomized, placebo-controlled clinical trial, modafinil effectively reduced EDS associated with obstructive sleep apnea/hypopnea syndrome (OSAHS). Patients (n=327) who met the International Classification of Sleep Disorders criteria for OSAHS and still had excessive sleepiness despite effective treatment with CPAP were randomized to receive 200 mg/day oral modafinil, 400 mg/day oral modafinil, or placebo. Patients continued treatment with CPAP throughout the study. At the 12-week study endpoint, patients in either modafinil group had significant improvements in sleep latency (assessed by the Maintenance of Wakefulness Test, $p < 0.001$) and clinical status (assessed by the Clinical Global Impression of Change score, $p < 0.001$) compared with placebo. There were no significant differences between the 200 mg/day and 400 mg/day modafinil groups.

Shift Work Sleep Disorder:

- A randomized, placebo-controlled clinical trial demonstrated that modafinil improved objective measurements of sleepiness and performance in patients with chronic shift work sleep disorder (SWSD); however, improvements were not restored to normal daytime levels. Eligible patients (n=209, age: 18 to 60 years) met the International Classification of Sleep Disorders criteria for SWSD, were symptomatic for at least 3 months, had excessive sleepiness at the time of their night shifts, worked a minimum 5 night shifts per month, and had documented daytime insomnia. Patients were randomized to receive either oral modafinil (200 mg per day before the start of each night shift) or placebo during the 12 week trial. Both sleep latency (assessed by the Multiple Sleep Latency Test) and sleepiness during night shift (assessed by the Clinical Global Impression of Change) were significantly improved in the modafinil group compared with placebo at the study endpoint. At least minimal improvement in sleepiness during the night shift was reported in 75% of patients on modafinil and 36% of patients on placebo ($p < 0.001$). Daytime sleep, assessed using polysomnography, did not differ between the modafinil and placebo groups. As recorded in patient's diaries, there was no difference between modafinil and placebo in the number of unintentional sleep episodes during night shift and during commute home ($p=0.2$ and 0.24, respectively), number of intentional sleep episodes during night shift ($p=0.13$), and reports of mistakes, accidents, or near accidents during the night shift ($p=0.34$). Insomnia was more frequently reported with modafinil compared with placebo (6% vs. 0%, $p=0.01$). The authors of this study acknowledge that modafinil provides limited benefit.

Multiple Sclerosis:

- The evidence for efficacy in Multiple Sclerosis is inconclusive. In a 5-week, randomized, double-blind, parallel-group, placebo controlled study (n=115) and the 8-week, randomized, double-blind, placebo-controlled, Hamburg Vigil Study (HAGIL; n=121), although improvements were noted from baseline to the end of the study period for both groups, there was no significant difference in the mean global Modified Fatigue Impact Scale score and Fatigue Severity Scale (FSS) score, respectively, between modafinil and placebo for the treatment of fatigue associated with multiple sclerosis (MS). Interestingly, in a 9-week, phase 2, single-blind, 2-center, pilot study (n=72), 2 weeks of modafinil 200 mg daily significantly improved FSS scores compared with placebo in patients with MS, but there was no significant difference between groups in FSS scores after continued modafinil dosing at 400 mg daily.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 1 (generic); Tier 3 (brand)
Commercial Formulary:	Tier 1 (generic; Tier 3 (brand)
Medicare Part D coverage:	Tier 2 (generic); Tier 4 (brand)

COVERAGE CRITERIA

Provigil (modafinil) meets the definition of **medical necessity** for the following:

- Narcolepsy (polysomnogram and MSLT required) to improve wakefulness in patients with EDS
- Excessive Daytime Fatigue related to:
    - Shift Worker's Sleep Disorder (documentation of shift work, excessive sleepiness at the time of the night shifts, and documented daytime insomnia required).
    - Obstructive sleep apnea as an adjunct to standard treatment(s) to improve excessive sleepiness, for the underlying obstruction (polysomnogram and documentation of Positive Airway Pressure therapy [CPAP, BPAP, APAP] use required). *Alternatively, can approve if documentation of use of an oral appliance instead of PAP.*
        - If trial of positive airway pressure therapy is not tolerated, documentation from the polysomnogram or patient's medical record is required).

- Fatigue related to Multiple Sclerosis is not an FDA or Compendia supported use. Evidence supportive of efficacy in patients with fatigue from MS is inconclusive. We require documentation from the patient's medical record that supports trial and either inadequate response or intolerance to one or more of the following drugs used for fatigue in MS:
    - Amantadine 100 mg twice a day - Caution must be taken in patients with renal insufficiency or seizure disorders.
    - Methylphenidate 10 to 60 mg per day, in two to three divided doses.
    - Selective serotonin reuptake inhibitors (e.g. fluoxetine 10 to 20mg/day) for treating the depressive symptoms and fatigue associated with MS.

Provigil (modafinil) is considered **experimental** for any indication that is not FDA approved or Compendia supported including the following:

- Attention deficit hyperactivity disorder
- Bipolar Disorder
- Delirium
- Depression
- Fibromyalgia
- Parkinson's disease
- Schizophrenia; Adjunct
- Sleep deprivation
- Somnolence due to adverse reaction to a drug
- Spastic cerebral palsy
- Steinert myotonic dystrophy syndrome
- Traumatic Brain Injury (TBI)

Required Provider Specialty:

- Original diagnosis of the sleep disorder must be made and documented by a Neurologist or Sleep disorder specialist.
    - Subsequent requests for the medication may be made by a primary care doctor.

DOSAGE/ADMINISTRATION

- **Narcolepsy:** 200 mg ORALLY once daily in the morning; doses up to 400 mg have been used
- **Obstructive sleep apnea; Adjunct**: 200 mg ORALLY once daily in the morning; doses up to 400 mg have been used
- **Shift work sleep disorder:** 200 mg ORALLY once daily 1 hour before start of work shift; doses up to 400 mg have been used

PRECAUTIONS:

- Angioedema, multiorgan hypersensitivity reaction, and anaphylactoid reactions have been reported
- Steroidal contraceptives, concomitant and one month after discontinuation; effectiveness reduced, alternative contraception recommended
- Depression, mania, psychosis or suicidal ideation, history of; increased risk of psychiatric adverse effects
- Elderly patients; drug clearance may be reduced
- Hepatic impairment, severe, with or without cirrhosis; drug clearance may be reduced
- Left ventricular hypertrophy, history of; increased risk of cardiac adverse events
- Mitral valve prolapse with CNS stimulant use; increased risk of cardiac adverse events

- Rash, serious or life-threatening including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug rash with eosinophilia and systemic symptoms have been reported
- Sleepiness, abnormal or excessive; previous level of wakefulness may not return to normal

COST

AWP (March 2010):
- 100 mg (30): $323.70; 200 mg (30): $489.90

AWP (February 2012):
- 100 mg (30): $612.00; 200 mg (30): $924.00

Generic MAC (March 2013):
- 100 mg (30): $352.20; 200 mg (30): $558.00

Generic MAC (October 2013):
- 100mg (30): $297.00; 200mg (30): $442.20

Generic MAC (June 2014):
- 100mg (30): $214.20; 200mg (30): $304.20

Provigil became available as a generic March 2013. Modafinil is considered a high cost generic.

COMMITTEE APPROVAL:

July 28, 2010
November 13, 2013 – approved new prior authorization criteria

GUIDELINE UPDATE INFORMATION:

03/2010	Policy creation
01/2011	Added background for non-FDA approved covered uses
10/26/2013	Prior authorization and coverage criteria updated
7/10/2014	Prior authorization created for Medicare Part D

REFERENCES:

- DRUGDEX®, accessed 03/29/2010, 01/14/2011, 10/26/2013.
- Product Information: Provigil® (modafinil). Cephalon, Inc., West Chester, PA, 2004.