Updated: 01/2019
PARP Approved: 1/2019

Gateway Health
Prior Authorization Criteria
Modafinil

Grandfather provision: Prior authorization will apply to new starts only.

All initial requests for Modafinil require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Modafinil Prior Authorization Criteria:

For initial requests for Modafinil all of the following criteria must be met:

- The diagnosis is one of the following:
  - Narcolepsy
  - Obstructive sleep apnea/hypopnea syndrome
  - Shift-work sleep disorder
  - Fatigue secondary to Multiple Sclerosis
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Coverage may be provided with a diagnosis of Narcolepsy (with or without Cataplexy) and the following criteria is met:

- Member is at least 7 years of age or older
- Documentation within any time frame that the member has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following:
  - Cerebrospinal fluid (CSF) hypocretin-1 deficiency one-third less than normal or <110 pg/mL
  - Polysomnogram sleep study test with REM sleep latency ≤ 15 minutes
  - Multiple sleep latency testing with a mean sleep latency ≤ 8 minutes with ≥ 2 sleep onset REM sleep periods (SOREMP)
- The member experienced therapeutic failure of at least two stimulants (e.g. amphetamine, methamphetamine, dextroamphetamine and methylphenidate containing products which may require prior authorization) or have a documented clinical rational as to why a stimulant cannot be used
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Documentation the member has experienced an improvement in symptoms
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of Obstructed Sleep Apnea/Hypopnea Syndrome (OSAHS) and the following criteria is met:

- Member is at least 16 years of age or older
- Documentation of diagnosis by at least one of the following tests: Polysomnogram, Apnea Hypopnea Index and/or a Respiratory Disturbance Index (RDI) score showing greater than 5 obstructive apneas per hour, each greater than 10 seconds in duration
- Must have documentation from the physician that the member is compliant with using a CPAP (continuous positive airway pressure) machine on a regular basis, defined by at least four (4) hours a night on at least 70% of the nights
- Must have documentation from the physician that the CPAP machine failed to resolve excessive daytime sleepiness documented by either Epworth Sleepiness Scale greater than 10 or Multiple Sleep Latency Test less than 6 minutes
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Documentation the member has experienced an improvement in symptoms
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of Shift-work Sleep Disorder (SWSD) and the following criteria is met:

- Member is at least 16 years of age or older
- Documentation of the member's recurring work schedule with a minimum of 5 night shifts per month
- Documentation the shift work results in sleepiness on the job or insomnia at home which interferes with activities of daily living
- Primary symptoms are associated with a work period (particularly night shift) that occurs during the habitual sleep phase
- Documentation of a polysomnography and the Multiple Sleep Latency Test (MSLT) demonstrate loss of a normal sleep-wake pattern (e.g., disturbed chronobiological rhythmicity)
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Documentation the member has experienced an improvement in symptoms
    - Documentation is submitted showing the member's recurring work schedule showing a minimum of 5 night shifts per month
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of Fatigue secondary to Multiple Sclerosis and the following criteria is met:

Members with historical pharmacy claims data meeting the following criteria will receive automatic authorization at the pharmacy point of service without the requirement for documentation of additional information. If pharmacy claims data cannot obtain the criteria below, documentation will be required to indicate the member meets the criteria. Claims will automatically adjudicate on-line, without a requirement to submit for prior authorization when the following criteria is met:

- Member is at least 16 years of age or older

- Member is receiving, or is intolerant to, treatment for multiple sclerosis (any medication FDA indicated for multiple sclerosis)
- Member has tried and failed or had an intolerance to amantadine
- When criteria has been met, benefit of coverage will be for 12 months.

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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PROVIGIL (modafinil)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Frequency:	Duration:	
Is the member currently receiving requested medication? ☐ Yes ☐ No		Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:

☐ **Narcolepsy**	Is the patient receiving concurrent treatment with a sedative hypnotic? ☐ Yes ☐ No Is a sleep study attached? ☐ Yes ☐ No Has the member tried and failed at least two stimulants? ☐ Yes ☐ No (If yes, list below) If no, provide clinical rationale as to why stimulants cannot be used: _____ _____
☐ **Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS)**	Is the patient receiving concurrent treatment with a sedative hypnotic? ☐ Yes ☐ No Is a sleep study attached? ☐ Yes ☐ No Please provide documentation of patient's compliance with a CPAP machine.
☐ **Shift-work Sleep Disorder**	Please provide documentation of the member's recurring work schedule. Please provide chart documentation that shift-work results in sleepiness on the job or insomnia at home that interferes with daily living. Are there any other medical, mental, or sleep disorders that could account for symptoms of excessive sleepiness? If yes, please list: ☐ Yes ☐ No _____
☐ **Fatigue secondary to Multiple Sclerosis (MS)**	Is the member on an agent to treat multiple sclerosis? ☐ Yes ☐ No Has the member had a trial and failure of amantadine? ☐ Yes ☐ No If no, provide clinical rationale as to why amantadine cannot be used: _____ _____

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PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

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MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REFERENCE VALUES

Lab	Initial (Pre-Treatment) Score	Date	Post-Therapy Score (Reauthorization only)	Date
Maintenance of Wakefulness Test (MWT) [for Narcolepsy or OSAHS only)				
Epworth Sleepiness Scale (ESS) [for OSAHS only]				
Multiple Sleep Latency Test (MSLT) [not necessary for Chronic Fatigue secondary to MS]				

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why / Current)

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date