Updated: 08/2019
DMMA Approved: 08/2019

Request for Prior Authorization for Provigil (modafinil) and Nuvigil (armodafinil)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Provigil (modafinil) and Nuvigil (armodafinil) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Provigil (modafinil) and Nuvigil (armodafinil) Prior Authorization Criteria:
For all requests for Provigil (modafinil) and Nuvigil (armodafinil) all of the following criteria must be met:

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- The request is for a FDA-approved or medically accepted indication including:
  - Narcolepsy (with or without cataplexy)
  - Obstructive Sleep Apnea/Hypopnea Syndrome
  - Shift-work Sleep Disorder
  - Fatigue secondary to Multiple Sclerosis (Provigil only)
- The member is not receiving concurrent treatment with a sedative hypnotic for the diagnosis of Narcolepsy or Obstructive Sleep Apnea/Hypopnea Syndrome.

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

- If requesting Provigil (modafinil), the member is at least 7 years of age
- If requesting Nuvigil (armodafinil), the member is at least 16 years of age
- 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 there is documented clinical rationale 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

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

- The member is at least 16 years of age
- OSAHS is documented 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 demonstrated by either Epworth Sleepiness Scale (ESS) 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 and the following criteria is met:

- The member is at least 16 years of age
- Member has chronic excessive sleepiness for at least 3 months
- There is documentation of the member's recurring work schedule with a minimum of 5 night shifts per month
- Documentation is provided that indicates 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 (i.e., 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 Chronic Fatigue due to Multiple Sclerosis and the following criteria is met:

- The member is at least 16 years of age
- The member is receiving, or is intolerant to, treatment for multiple sclerosis
- The member experienced a trial and failure of amantadine
- **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 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.

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PROVIGIL (modafinil) and NUVIGIL (armodafinil)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6253 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:
Health Options 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:
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

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:

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]				

SUPPORTING INFORMATION or CLINICAL RATIONALE

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PROVIGIL (modafinil) and NUVIGIL (armodafinil)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
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PHONE: (844) 325-6253 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

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) (Provigil only)**	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: _____ **For reauthorization only:** Has the member experienced an improvement in symptoms? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

Prescribing Provider Signature	Date