

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.

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
- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- 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 <u>diagnosis</u> of Narcolepsy (with or without Cataplexy) and the following criteria is met:

- 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
 - o Polysomnogram sleep study test with REM sleep latency ≤ 15 minutes
 - O Multiple sleep latency testing with a mean sleep latency ≤ 8 minutes with ≥ 2 sleep onset REM sleep periods (SOREMP)
- **Initial Duration of Approval:** 12 months
- Reauthorization criteria
 - o Documentation the member has experienced an improvement in symptoms
- **Reauthorization Duration of approval:** 12 months

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

- 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
 - o Documentation the member has experienced an improvement in symptoms
- Reauthorization Duration of approval: 12 months

Coverage may be provided with a <u>diagnosis</u> of Shift-work Sleep Disorder and the following criteria is met:

- 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 sleep log or actigraphy for at least 14 days
- **Initial Duration of Approval:** 12 months
- Reauthorization criteria
 - o Documentation the member has experienced an improvement in symptoms
 - O 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 <u>diagnosis</u> of Chronic Fatigue due to Multiple Sclerosis and the following criteria is met: (modafinil only)

- 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
 - o Documentation the member has experienced an improvement in symptoms
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided with a <u>diagnosis</u> of idiopathic hypersomnia if the following criteria is met:

- Documentation of a baseline Epworth Sleepiness Scale score OR documentation of a baseline Idiopathic Hypersomnia Severity Score
- Insufficient sleep syndrome is confirmed absent via at least a week of wrist actigraphy or lack of improvement after an adequate trial of increased nocturnal time in bed



- Documentation of a MSLT showing fewer than 2 SOREMPs, OR, no SOREMPs, if the REM latency on the preceding sleep study was ≥ 15 minutes
- Cataplexy is confirmed to be absent
- Must provide documentation of at least one of the following:
 - o MSLT shows a mean sleep latency of ≤8 minutes
 - o Total 24-hour sleep time is ≥660 minutes (typically 12 to 14 hours) on 24-hour polysomnography or by wrist actigraphy in association with a sleep log

Initial Duration of Approval: 3 months

Reauthorization criteria

 Documentation of an improvement in Epworth Sleepiness Scale score from baseline OR improvement in Idiopathic Hypersomnia Severity Score.

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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.



PROVIGIL (MODAFINIL) AND NUVIGIL (ARMODAFINIL) PRIOR AUTHORIZATION FORM

Please complete and	applicable to Highmark Health Options Pharmacy Services. FAX: (
	If needed, you may call to speak to a Pharmacy Services Repre						
	PHONE: (844) 325-6251 Monday through Friday 8:00am to						
	PROVIDER INFORMATION	7.00pm					
Requesting Provider:							
Provider Specialty:	Office Contact:						
Office Address:							
Office Address:	Office Fax:	Office Phone:					
MEMBER INFORMATION							
Member Name:	DOB:	1.4					
Member ID:	Member weight: Member heig	gnt:					
REQUESTED DRUG INFORMATION							
Medication:	-	Strength:					
Frequency:		Duration:					
		Date Medication Initiated:					
	eing used for a chronic or long-term condition for which the medication ma	y be necessary for the life of the patient?					
☐ Yes ☐ No							
	Billing Information						
This medication will							
	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:	Phone:					
	MEDICAL HISTORY (Complete for ALL requests	8)					
Diagnosis:							
	Is the patient receiving concurrent treatment with a sedative hypnorest hypnor						
Diagnosis: Narcolepsy	Is the patient receiving concurrent treatment with a sedative hypnoris a sleep study attached?						
	Is the patient receiving concurrent treatment with a sedative hypnorest hypnor	tic?					
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Narcolepsy	Is the patient receiving concurrent treatment with a sedative hypnoris a sleep study attached? For reauthorization only: Has the member experienced an improvement in symptoms? Is the patient receiving concurrent treatment with a sedative hypnorise.	tic?					
Narcolepsy Obstructive Slo	Is the patient receiving concurrent treatment with a sedative hypnoris a sleep study attached? For reauthorization only: Has the member experienced an improvement in symptoms? Is the patient receiving concurrent treatment with a sedative hypnoris a sleep study attached?	tic?					
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PRIOR AUTHORIZATION FORM (PAGE 2 of 2) MEMBER INFORMATION									
Member Name:		DOB:	ATION						
Member ID:		Member wei	ght:	pounds or	kg				
Fatigue secondary to Multiple Sclerosis (MS) (modafinil 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							
Idiopathic Hypersomnia		Is the member experiencing cataplexy? Yes \sum No Is the sleep study or actigraphy attached? Yes \sum No							
REFERENCE VALUES									
Lab	Initial (Pre-Treatment) Score	Date	Post-Therapy	Score (Reauthorizat	tion only)	Date			
Maintenance of Wakefulness Test (MWT) [for Narcolepsy or OSAHS only)									
Epworth Sleepiness Scale (ESS) [OSAHS and idiopathic hypersomnia]									
Idiopathic Hypersomnia Severity Score (idiopathic hypersomnia only)									
Multiple Sleep Latency Test (MSLT) [not necessary for Chronic Fatigue secondary to MS]									
CURRENT or PREVIOUS THERAPY									
Medication Name	Strength/ Frequency	Dates o	Dates of Therapy Status (Discontinued & Why / Curren		Current)				
SUPPORTING INFORMATION or CLINICAL RATIONALE									
SUFFURTING INFORMATION OF CLINICAL RATIONALE									
Prescribing P			Date						